

## **Guidelines**

### **World Guidelines for Groin Hernia Management**

The HerniaSurge Group

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#### **Conflict of Interest / Disclaimer**

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They are based purely on the best available evidence and expert opinion. All HerniaSurge members are active in the scientific community. An additional course was given to all involved members to guarantee unbiased literature searches and review.

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## **Abstract**

### **Introduction**

Worldwide, more than 20 million patients undergo groin hernia repair annually. The many different approaches, treatment indications and a significant array of techniques for groin hernia repair warrant guidelines to standardize care, minimize complications, and improve results.

The main goal of these guidelines is to improve patient outcomes, specifically to decrease recurrence rates and reduce chronic pain, the most frequent problems following groin hernia repair.

### **Methods**

An expert group of international surgeons (the HerniaSurge Group) and one anesthesiologist pain expert was formed. The group consisted of members from all continents with specific experience in hernia-related research. Care was taken to include surgeons who perform all different types of repair and had preferably performed research on groin hernia surgery. During the Group's first meeting, Evidence-Based Medicine (EBM) training occurred and 166 key questions (KQ) were formulated. EBM rules were followed in complete literature searches (including a complete search by The Dutch Cochrane database) to January 1, 2015 and to July 1, 2015 for level 1 publications.

The articles were scored by teams of two or three according to Oxford, Sign and Grade methodologies. During five two-day meetings, results were discussed with the working group members leading to 125 statements and 86 recommendations. Statements graded as "strong" lead to recommendations. Those graded as "weak" lead to suggestions. In the Results and Summary section below, the term "should" refers to a recommendation.

Finally, consensus was sought by putting 50 "**KEY**" statements and recommendations to a vote by all HerniaSurge members. The AGREE II instrument was used to validate the guidelines. An external review was performed by three international experts.

### **Results and Summary**

Inguinal hernia (IH) risk factors include: family history, previous contra-lateral hernia, gender, age, abnormal collagen metabolism, prostatectomy, and low body mass index. Perioperative risk factors for recurrence like: poor surgical technique, low surgical volume, and surgical inexperience should be considered when treating IH patients.

IH diagnosis can be confirmed by physical examination alone in the vast majority of patients with appropriate signs and symptoms. Rarely, ultrasound is necessary. Less commonly still, an MRI, CT scan or herniography may be needed.

The EHS classification system is suggested to stratify IH patients for tailored treatment, research and audit. Symptomatic groin hernias should be treated surgically. Asymptomatic or minimally symptomatic male IH patients may be managed with “watchful waiting” since their risk of hernia-related emergencies is low. The majority of these individuals will eventually require surgery; therefore, surgical risks and the watchful waiting strategy should be discussed with patients. Surgical treatment should be tailored to the surgeon’s expertise, patient- and hernia-related characteristics and local/national resources.

Mesh repair is recommended as first choice, either by an open procedure or a laparo-endoscopic repair technique. One standard repair technique for all groin hernias does not exist. It is recommended that surgeons/surgical services provide both anterior and posterior approach options. HerniaSurge suggests Lichtenstein or laparo-endoscopic repair as optimal techniques. Provided that resources and expertise are available, laparoscopic techniques have faster recovery times, lower chronic pain risk and are cost effective. There is discussion concerning laparo-endoscopic management of potential bilateral hernias (occult hernia issue). After patient consent, during TAPP, the contra-lateral side can be inspected. This is not suggested during unilateral TEP repair.

Day surgery is recommended for simple groin hernia repair provided aftercare is organized and suggested for selected other cases (e.g. after local anesthetic in ASA IIIa patients).

Surgeons should be aware of the intrinsic characteristics of the meshes they use. Use of so-called low-weight mesh may have short-term benefits like reduced postoperative pain and shorter convalescence, but are not associated with better longer-term outcomes like recurrence and chronic pain. Mesh selection on weight alone is not recommended. Migration and/or erosion incidence seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques. In almost all cases, mesh fixation in TEP is unnecessary. In both TEP and TAPP it is recommended to fix mesh in M3 hernias (large medial) to reduce recurrence risk.

Antibiotic prophylaxis in average-risk patients in low-risk environments is not recommended. In laparo-endoscopic repair it is never recommended.

Local anesthesia in open repair has many advantages and its use is suggested (especially in patients with severe systemic disease) provided the surgeon is experienced in this technique. General anesthesia is suggested over regional as it allows for faster discharge with fewer complications like urinary retention, myocardial infarction, pneumonia and thromboembolism. Perioperative field blocks are recommended in all cases of open repair.

An early return to normal activities can be safely recommended.

Provided expertise is available, it is suggested that women with groin hernias undergo laparo-endoscopic repair in order to decrease chronic pain risk and avoid missing a femoral hernia. Watchful waiting is suggested in pregnant women as groin swelling most often consists of self-limited round ligament varicosities. Timely mesh repair by a laparo-endoscopic approach is suggested for femoral hernias provided expertise is available.

All complications of groin hernia management are discussed in an extensive chapter on the topic (chapter 18). Chronic postoperative inguinal pain (CPIP) is a serious complication affecting 10-12% of IH repair patients. It is defined as bothersome moderate pain impacting daily activities lasting at least 3 months postoperatively. CPIP risk factors include: young age, female gender, high preoperative pain, early high postoperative pain, recurrent hernia and open repair. Chapter 19 covers CPIP prevention and treatment. In short, the focus should be on nerve recognition in open surgery and, in selected cases, prophylactic pragmatic nerve resection (Planned resection is not suggested.). It is suggested that CPIP management be performed by multi-disciplinary teams. It is also suggested that CPIP be managed by a combination of pharmacological and interventional measures and, if this is unsuccessful, followed by, in selected cases, (triple) neurectomy and (in selected cases) mesh removal.

For recurrent hernia after anterior repair, posterior repair is recommended. If recurrence occurs after a posterior repair, an anterior repair is recommended. After a failed anterior and posterior approach, management by a hernia specialist surgeon is recommended.

Risk factors for hernia incarceration/strangulation include: female gender, femoral hernia presence and a history of hospitalization related to groin hernia. It is suggested that treatment of emergencies be tailored according to patient- and hernia-related factors, local expertise and resources.

Learning curves vary between different techniques. Probably about 100 supervised laparo-endoscopic repairs are needed to achieve the same results as open mesh surgery like Lichtenstein. It is suggested that case load per surgeon is more important than center volume. It is recommended that minimum requirements be developed to certify individuals as expert hernia surgeon. The same is true for the designation “Hernia Center.”

From a cost-effectiveness perspective, day-case laparoscopic IH repair with minimal use of disposables is recommended.

The development and implementation of national groin hernia registries in every country (or region, in the case of small country populations) is suggested. They should include patient follow-up data and account for local healthcare structures.

A dissemination and implementation plan of the guidelines will be developed by global (HerniaSurge), regional (international societies) and local (national chapters) initiatives through internet websites, social media and smartphone Apps. An overarching plan to improve access to safe IH surgery in low resource settings (LRSs) is needed. It is suggested that this plan contains simple guidelines and a sustainability strategy allowing implementation and maintainability, independent of international aid. It is suggested that in LRSs the focus be on performing high-volume Lichtenstein repair under local anesthesia using low-cost mesh.

Three chapters (29, 30, and 31) discuss future research, guidelines for general practitioners and guidelines for patients.

## **Conclusions**

The HerniaSurge Group has developed these extensive and inclusive guidelines for the management of adult groin hernia patients. It is hoped that they will lead to better outcomes for groin hernia patients wherever they live! More knowledge, better training, national audit and specialization in groin hernia management will standardize care for these patients, lead to more effective and efficient healthcare and provide direction for future research.

## **Key Words:**

Inguinal hernia, inguinal hernia treatment, guidelines, groin hernia management



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# PART 1

## Management of Inguinal Hernias in Adults

### Chapter 1

#### HerniaSurge: The World Guidelines for Groin Hernia Management

M.P. Simons, N. van Veenendaal, H.M. Tran, B.J. van den Heuvel and H.J. Bonjer

#### Introduction

Lifetime occurrence of groin hernia—viscera or adipose tissue protrusions through the inguinal or femoral canal—is 27 to 43% in men and 3 to 6% in women<sup>1</sup>. Inguinal hernias are almost always symptomatic; and the only cure is surgery<sup>2</sup>. A minority of patients are asymptomatic but even a watch-and-wait approach in this group results in surgery in approximately 70% within five years<sup>2</sup>.

Worldwide, inguinal hernia repair is one of the most common surgeries, performed on more than 20 million people annually<sup>1</sup>. Surgical treatment is successful in the majority of cases but recurrences necessitate reoperations in 10-15% and long-term disability due to chronic pain (moderate pain lasting longer than 3 months) occurs in 10-12% of patients. Approximately 1-3% of patients have severe chronic pain. This has a tremendous negative effect globally on health and healthcare costs.

However, better outcomes are definitely possible. Our objective is to improve groin hernia patient care worldwide by developing and globally distributing standards of care based on all available evidence and experience.

Currently, groin hernia treatment is not standardized. Three hernia societies have separately published guidelines aimed at both improving treatment and enhancing the education of surgeons involved in groin hernia treatment. In 2009, the European Hernia Society (EHS) published guidelines covering all aspects of inguinal hernia treatment in adult patients<sup>3</sup>. The EHS guidelines were updated in 2013<sup>4</sup>. The International Endoscopic Hernia Society (IEHS) published guidelines in 2011 covering laparo-endoscopic groin hernia repair<sup>5</sup>. In 2013, the European Association for Endoscopic Surgery (EAES) published guidelines focused on aspects of laparo-endoscopic treatments<sup>5,6</sup>. These three societies began collaborating in 2014, concluding it was both necessary and logical to develop a universal set of guidelines for groin hernia treatment. “Groin Hernia Guidelines” was selected as the name for the collaborative effort since information on femoral hernias was including for the first time. A movement was launched to develop a state-of-the-art series of guidelines spearheaded by passionate hernia experts for all aspects of abdominal wall hernia treatment. The European societies—EHS, IEHS and EAES—invited scientific societies worldwide with a focus on groin hernias to participate. The project was named “HerniaSurge,” ([www.herniasurge.com](http://www.herniasurge.com)) forged from the combination of “hernia” and “surge” as a metaphor for waves crossing all continents.

## Evolution of Groin Hernia Surgery

The first groin hernia surgeries were done during the end of the 16<sup>th</sup> century. They involved hernia sac reduction and resection and posterior wall reinforcement of the inguinal canal by approximating its muscular and fascial components. Subsequently, many hernia repair variants were introduced. Prosthetic material utilization commenced in the 1960s, initially only in elderly patients with recurrent inguinal hernias. Favorable long-term results of these mesh repairs encouraged adoption of mesh repair in younger patients. Presently, the majority of surgeons in the world favor mesh repair of inguinal hernias. In Denmark, with its complete IH repair statistics in a national database, mesh use was close to 100% in 2013<sup>7</sup>. In Sweden, mesh use is above 99%. In the early 1980s, minimally-invasive techniques for groin hernia repair were first done and reported on in the scientific literature, adding another management modality. Laparoscopic Trans Abdominal Preperitoneal (TAPP) and Totally Extra Peritoneal (TEP) endoscopic techniques, collectively, “laparo-endoscopic surgery,” have been developed as well.

The fact that so many different repairs are now done strongly suggests that a “best repair method” does not exist. Additionally, large variations in treatments result from cultural differences amongst surgeons, different reimbursement systems and differences in resources and logistical capabilities.

Surgeons searching for “best” treatment strategies are challenged by a vast diverse scientific literature, much of which is difficult to interpret and apply to one’s local practice environment. As noted, hernia repair techniques vary broadly, dependent upon setting. Mesh use probably varies from 0-5% in low-resource settings to 95% in settings with the highest resources. Currently, open mesh repair (mainly Lichtenstein repair) is still most frequently used.

Laparo-endoscopic surgery use varies from zero to a maximum of approximately 55% in some high resource countries. The average use in high resource countries is largely unknown except for some examples like Australia (55%)<sup>8</sup>, Switzerland (40%)<sup>9</sup>, the Netherlands (45%) and Sweden (28%)<sup>10</sup>. Sweden has a national registry with complete coverage. Interesting are the following percentages for the year 2015: Lichtenstein 64%, TEP 25%, TAPP 3%, open pre-peritoneal mesh 3.3%, combined open and pre-peritoneal 2.7% and tissue repair in 0.8%. The German Herniamed registry which contains data on about 200,000 patients (not complete national coverage so possibly biased) contains interesting information confirming that a wide variety of techniques are in use. The percentages over the period 2009-16 were: TAPP 39%, TEP 25%, Lichtenstein 24%, Plug 3%, Shouldice 2.6%, Gilbert PHS 2.5% and Bassini 0.2%. Other reliable data from Asia and America are lacking and often outdated once published. Table 1 indicates current hernia repair technique.

Table 1. Current inguinal hernia repair techniques

Non-mesh techniques	Shouldice Bassini (and many variations) Desarda
Open mesh techniques*	Lichtenstein Trans inguinal pre-peritoneal (TIPP) Trans rectal pre-peritoneal (TREPP) Plug and patch

	PHS (bilayer) Variations
Endoscopic techniques	Totally extra-peritoneal (TEP) Trans abdominal pre-peritoneal repair (TAPP) Single incision laparoscopic repair (SILS) Robotic repair

\*These can be modified; and different types of mesh are in use.

## Future Directions

Standardizing groin hernia repairs and improving outcomes requires that many questions be answered. Best operative techniques should have the following attributes: low incidence of complications (pain and recurrence), relatively easy to learn, fast recovery, reproducible results, and cost effectiveness. Treatment of groin hernia patients will improve if we honor all stakeholders' interests (patients, hospitals, surgeons, industry and insurers).

Worldwide, groin hernia surgery outcomes need improvement. Recurrence rates—as measured by the proxy of reoperations—still range from 10 to 15%; although the increasing use of mesh has resulted in falling recurrence rates<sup>11</sup>. There are great concerns about the complication of chronic pain which still occurs in 10 to 12% of patients.

## Our Process

The HerniaSurge guidelines that follow have been developed to address all questions concerning groin hernia repair in adults, worldwide. They contain recommendations for all groin hernia types, in all kinds of patients, in all parts of the world. It has been written by and endorsed by experts from every continent and from all the major hernia societies – European, Americas, Asia-Pacific, Afro-Middle-East and Australasian. Fifty expert surgeons from 19 countries crafted these state-of-the-art guidelines. We consider this work a “living document,” open to interpretation, modification and improvement over time as experience and knowledge grows.

The involved experts have extensive clinical and scientific experience and a combined scholarly output of hundreds of publications focused on various aspects of groin hernia management. They are experienced in open non-mesh, open mesh and both TEP and TAPP techniques. The HerniaSurge steering committee has done its best to include and honor all treatment approaches, without prejudice and self-interest. Although evidence in the scientific literature forms the foundation for the guidelines we incorporated patients' wishes, surgeon's expectations and industry's involvement. Factors like financial resources and logistics were taken into account as well. Our aim was to offer unbiased guidance to all surgeons and patients wherever they reside.

## Acknowledgement

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## Guideline Formulation

The HerniaSurge guidelines are developed according to the AGREE instrument II (Appraisal of Guidelines for Research and Evaluation). They are not a textbook, so extensive background information is not included. However, they represent the results of an extensive literature search spanning to 1 January 2015 for systematic reviews and to 1 July 2016 for randomized controlled trials and best evidence. During five two-day meetings (Amsterdam April 2014, Edinburgh June 2014, Warsaw October 2014, Cologne February 2015 and Milano May 2015) and a four-day meeting in Amsterdam in September 2015, a standard evidence-based process was rigorously used. Teams of three HerniaSurge members performed standard search strategies and scored greater than 3,500 articles according to Oxford, SIGN and grade methodology<sup>12,13</sup>. Level of evidence was first graded up or down by teams and later in all recommendations by the whole committee. Then, the Statements and Recommendations were developed and these were also graded during three consensus meetings. Statements are scored according to the levels very low, low, moderate or high. The recommendations contain the terms "recommend" when strong and "suggest" when weak. The grading consists of moving up or down in level after discussing the evidence in HerniaSurge meetings. The first consensus was sought within the committee of 50 surgeons. The second consensus was sought via the internet and the final consensus will be sought during the EHS Rotterdam meeting in June 2016. This will be published separately. This strategy led to some very strong recommendations that not only reflect the evidence in literature but truly reflect the opinions of 50 international leaders in groin hernia surgery. Expert opinion in this case is the opinion of the entire committee. For some important recommendations, long and passionate discussions led to the consensus found in these guidelines. Our discussions transcended countries and cultures and withstood pressures from finance and/or industry-motivated opinions. Statements and recommendations sometimes strongly favor certain treatments but not are necessarily suited to use in all parts of the world depending on local tradition, training capabilities and/or resources. The adage applies that any technique, thoroughly taught and frequently performed with good results, is valid. Some techniques are easily learned and offer good results whilst others might be very difficult to master but offer great results. All these techniques are highly dependent on the surgeon's knowledge of anatomy, caseload and dedication to groin hernia surgery.

All search strategies, PRISMA results, tables with articles and background information will be published on HerniaSurge's website ([www.herniasurge.com](http://www.herniasurge.com)). All articles are filed per chapter in Mendeley<sup>R</sup> reference manager.

We would like to emphasize the fact that the "World Guidelines for the Management of Adult Groin Hernias" is NOT a legal document, merely guidelines. If surgeons choose not to follow strong recommendations, they should do so in consultation with their patients and document this in the medical record.

HerniaSurge encourages the establishment of local and national registries because they are valuable for audit and research. HerniaSurge predicts an increase in training of hernia specialist surgeons and the formation of hernia centers but acknowledges that training and educating general surgeons who work in general practice in the short-term will have a greater impact on the results of groin hernia surgery. Furthermore, HerniaSurge is committed to develop E-learning modules and a "HerniaSurge App" to aid surgeons and patients around the world.

The HerniaSurge Group has formulated a large number of new research questions. The guidelines will be updated every two years as new evidence is published. The expiration date for this document is June 1, 2018.

## Chapter 2 Risk Factors for the Development of Inguinal Hernias in Adults

L.N. Jorgensen, W.W. Hope, and T. Bisgaard

### Introduction

Numerous risk factors exist for the development of primary inguinal hernias (IH) and recurrent inguinal hernias (RIH) in adults, some better studied than others. These risk factors span a range, from acquired to genetic and modifiable to immutable. Some are under the surgeon's control, but many are not.

For the purposes of this chapter (unless stated otherwise), IH repair is considered synonymous with IH diagnosis. The studies referenced below do not distinguish between open and laparoscopic repairs or between direct and indirect hernias. Femoral hernias are not considered in this review nor are IHS in children except for a brief mention.

### Key Questions

**KQ02.a** What are the risk factors for the development of primary inguinal hernias in adults?

**KQ02.b** What are the acquired, demographic and perioperative risk factors for recurrence after treatment of IH in adults?

### Statements and Recommendation

Statement	Important intrinsic risk factors for the development of primary inguinal hernias include: inheritance, a previous contralateral hernia, gender, age and abnormal collagen metabolism.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Statement	Important acquired risk factors for the development of primary inguinal hernias are prostatectomy and low body mass index.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Statement	Future studies on primary inguinal hernia formation should consider these inborn and acquired risk factors.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Statement	Several important intrinsic/demographic (anatomy, female gender, abnormal collagen metabolism), acquired (obesity), and perioperative risk factors (poor surgical technique, low surgical volume, surgical inexperience, and local anesthesia) for IH development exist.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

**Recommendation**

Intrinsic, acquired, surgical and perioperative risk factors are recommended to be strongly considered since they are potentially modifiable and can influence the type of repair performed.



Strong  
\*upgraded

## Evidence in Literature

A medical literature search for primary IH risk factors identified 989 studies. Included are a discussion of one systematic review, two randomized controlled trials (RCTs), 24 cohort or registry studies, five case-control studies and five diagnostic studies in the material below.

A medical literature search for RIH risk factors identified 1,191 studies. A discussion follows of two systematic reviews, two RCTs, 31 cohort or registry studies, one case-control study and four diagnostic studies.

### *Primary inguinal hernia*

The lifelong cumulative incidence of IH repair in adults is 27% - 42.5% for men and 3% - 5.8% for women<sup>14-17</sup>.

Risk factors associated with IH formation (evidence level – high):

- Inheritance (first degree relatives diagnosed with IH elevates IH incidence, especially in females)<sup>18-20</sup>
- Gender (IH repair is approximately 8-10 times more common in males)
- Age (peak prevalence at 5 years, primarily indirect and 70-80 years, primarily direct)<sup>16,21-23</sup>
- Collagen metabolism (a diminished collagen type I/III ratio)
- Prostatectomy history (especially open radical)<sup>24-36</sup>
- Obesity<sup>20,22,37-39</sup>

Risk factors associated with IH formation (evidence level – moderate):

- Primary hernia type (both indirect and direct subtypes are bilaterally associated)<sup>40</sup>
- Increased systemic levels of matrix metalloproteinase-2<sup>41-44</sup>
- Rare connective tissue disorders (e.g. Ehlers-Danlos syndrome)<sup>45</sup>



Risk factors associated with IH formation (evidence level – low):

- Race (IHs are significantly less common in black adults)<sup>22</sup>
- Chronic constipation<sup>20,46</sup>
- Tobacco use (inversely correlated with IH incidence)<sup>38</sup>
- Socio-occupational factors

There is contradictory evidence that social class, occupational factors and work load effect the risk of IH repair<sup>47,48</sup>. Heavy lifting may predispose to IH formation<sup>49</sup>.

Risk factors associated with IH formation (evidence level – very low):

- Pregnancy (actually not shown to be related to IH formation)<sup>20</sup>
- Pulmonary disease (COPD and chronic cough possibly increasing the risk of IH formation)<sup>49,50</sup>

Liver disease, renal disease and alcohol consumption have not been properly investigated to determine if they are risk factors for IH formation.

### *Recurrent inguinal hernia*

Risk factors for RIH with a high level of evidence include female gender<sup>50–60</sup>, direct versus indirect IH<sup>59,60</sup>, annual IH repair volume of less than five cases<sup>61</sup> and limited surgical experience<sup>57,62–69</sup>. However this last risk factor may be modifiable by surgical coaching<sup>70–73</sup>.

Risk factors for RIH with a moderate level of evidence include: presence of a sliding hernia<sup>74</sup>, a diminished collagen type I/III ratio<sup>41,75,76</sup>, increased systemic matrix metalloproteinase levels<sup>43,60,75,76</sup>, obesity<sup>38,60</sup> (although questioned in two very small studies<sup>58,77</sup>) and open hernia repair under local anesthesia by general surgeons<sup>54,78</sup>. A recent meta-analysis examining features of 100,000 to 200,000 repairs demonstrated that size (< 3cm versus  $\geq$  3 cm) and bilaterality did not affect the risk of recurrence<sup>60</sup>.

Incorrect surgical technique is likely the most important reason for recurrence after primary IH repair. Within this broad category of poor surgical technique are included: lack of mesh overlap, improper mesh choice, lack of proper mesh fixation, amongst others. Surgical risk factors are fully described elsewhere in this monograph.

Several other potential risk factors have not been well studied or have low or very low levels of evidence supporting an association. Early postoperative hematoma formation<sup>79</sup> and emergent surgery<sup>51,53,59,60</sup> may be risk factors for hernia recurrence but the association is not conclusive. Low (1-7 drinks/week) versus no ethanol consumption may protect against hernia recurrence. The effect of high ethanol consumption is unclear<sup>54</sup>. Increased age<sup>58,60,80,81</sup>, COPD<sup>58,60,77-83</sup>, prostatectomy<sup>77</sup>, surgical site infection<sup>79,84</sup>, cirrhosis<sup>85</sup>, chronic constipation<sup>77</sup>, a positive family history<sup>81,86</sup> and smoking<sup>54,58,81,86</sup> have not been consistently shown to be risk factors for RIH. Incompletely studied factors which may impact the risk of IH recurrence are chronic kidney disease, social class, occupation, work load, pregnancy, labor, race and postoperative seroma occurrence.

Conclusion: Several demographic (anatomy, female gender, abnormal collagen metabolism), acquired (obesity), and perioperative risk factors (insufficient surgical technique, low surgical volume, surgical inexperience and local anesthesia) for RIH were identified. Risk factors for IH and RIH are not comparable. In daily surgical practice, attention should be paid to perioperative surgical factors as they are modifiable. Allocation arms in future outcome studies should be balanced according to these demographic and acquired risk factors.

## **Chapter 3 Diagnostic Testing Modalities**

H. Niebuhr, M. Pawlak and M. Śmietański

### **Introduction**

History and clinical examination are usually all that are required to confirm the diagnosis of a clinically evident groin hernia. Imaging may be required if there is vague groin swelling and diagnostic uncertainty, poor localization of swelling, intermittent swelling not present at time of physical examination, and other groin complaints without swelling.

## Differential diagnosis of groin swellings

Inguinal	Inguinoscrotal	Femoral	Inguinofemoral	Scrotal
Inguinal hernia	Inguinal hernia	Femoral hernia	Inguinal lymph nodes	Skin: boils, sebaceous cysts, papillomas, warts
Lymph nodes	Hydrocele: encysted hydrocele of the cord, infantile hydrocele, hydrocele of the hernia sac	Lymph nodes	Distended psoas bursa	Subcut. tissue: lymph scrotum, filariasis Tunica vaginalis: hydrocele, pyocele, hematocele, chylocele
Encysted hydrocele of the cord	Spermatic cord: varicocele, funiculitis, lymph varix, diffuse lipoma of the cord, hematoma of the cord	Saphena varix	Effusion in the hip joint	Testis: Orchitis (acute/chronic), neoplasms
Undescended testis	Testis: undescended, ectopic testis	Ectopic testis		Epididymis: cysts, acute or chronic infections
In females or pregnant women: round ligament varicosis				Spermatic cord: varicocele, lymph varix

An apparent hernia with clear clinical features such as a reducible groin bulge with local discomfort usually requires no further investigation. However, when patients present with groin complaints and hernia is not clearly the diagnosis, the question arises about which imaging modality to use. Ultrasonography (US) is now widely available but magnetic resonance imaging (MRI), computed tomography (CT) and herniography may play a role as well. Laparoscopy is not generally considered part of the diagnostic process for groin complaints and bulges and is not considered further in this chapter.

## Key questions

**KQ03.a** Which diagnostic modality is the most suitable for diagnosing groin hernias?

**KQ03.b** Which diagnostic modality is the most suitable for diagnosing patients with obscure pain or doubtful swelling?

**KQ03.c** Which diagnostic modality is the most suitable for diagnosing recurrent groin hernias?

**KQ03.d** Which diagnostic modality is the most suitable for diagnosing chronic pain after groin hernia surgery?

## Recommendations

<i>Recommendation</i>	Clinical examination (CE) alone is recommended for confirming the diagnosis of an evident groin hernia.	☒☒☐☐	Strong *upgraded
<i>Recommendation</i>	CE and US combined is recommended as most suitable for diagnosing patients with vague groin swelling or possible occult groin hernias. Dynamic MRI or CT can be considered for further evaluation if US is negative or non-diagnostic.	☒☒☒☐	Strong *Upgraded
<i>Recommendation</i>	CE and US combined is suggested as most suitable for confirming the diagnosis of recurrent groin hernia. Dynamic MRI or CT can be considered for further evaluation if US is negative or non-diagnostic.	☒☒☐☐	Weak
<i>Recommendation</i>	The use of US-guided nerve blocks is suggested as most suitable for diagnosing the cause of chronic pain after inguinal hernia surgery. US, CT or MRI scans are helpful in identifying non-neuropathic causes of chronic groin pain (i.e. mesh-related pathologies, recurrent hernias, neuromas – occasionally).	☒☒☐☐	Weak

## Evidence in Literature

The criterion standard for hernia diagnosis is CE of the groin with a sensitivity of 0.745 and a specificity of 0.963 reported in a prospective cohort study from 1999<sup>87</sup>. Three consensus guidelines have been published on groin hernia treatment<sup>3,6,88</sup>. All published statements on diagnostic work-up are weak, mainly focusing on CE alone. Only groin pain that is obscure or groin swelling of unclear origin (possible occult hernia) are noted to require further diagnostic investigation<sup>89-91</sup>. No consensus exists presently on the best imaging modality for these diagnostic dilemmas.

CE alone can miss hernias, especially those that are small, (e.g. femoral hernias in obese women and men) and multiple hernias where only some of the hernias are apparent with physical examination<sup>92</sup>. US, MRI, CT and herniography have all been studied in various settings in an attempt to close this “diagnostic gap”<sup>89,93-106</sup>.

Two RCTs with a total of 510 patients showed that US is highly sensitive and a useful way to identify hernias<sup>89,98</sup>. Several other studies have echoed this finding<sup>91,102,103,105</sup>.

The 1999 prospective cohort study showed that US had a specificity of 0.945 and a sensitivity of 0.815 for detecting groin hernias<sup>87</sup>. MRI demonstrated a specificity of 0.963 and a sensitivity of 0.945<sup>87</sup>. A 2013 meta-analysis revealed that groin US had a specificity of 0.86 and a sensitivity of 0.77<sup>107</sup>.

Two RCTs support the use of CE in combination with US to confirm the diagnosis of inguinal hernias. CE plus US was found to be superior to CE alone in both trials<sup>91,98</sup>.

Another RCT and a prospective cohort study—both of low quality—showed that US performed poorly in the detection of occult groin hernias<sup>108,109</sup>. Both studies did recommend the use of US for interval assessment of patients with equivocal findings since those with equivocal findings are ultimately proven to have a high incidence of groin hernias.

In conclusion, challenging hernia diagnoses like femoral and clinically occult hernias can be evaluated with US since it is: routinely available, relatively specific, cost effective, repeatable, useful in diagnosing other conditions, delivers no ionizing radiation and well accepted by patients<sup>87,89–92,108–116</sup>.

In pregnant women, color-duplex US is useful for an entity presenting with an inguinal lump and pain, round ligament varicosity<sup>111,117,118</sup>.

When groin US is negative or non-diagnostic, dynamic MRI, dynamic CT and even herniography may be considered in an attempt to establish a diagnosis<sup>119</sup>. Dynamic in this context refers to Valsalva maneuver during testing in an attempt to force a possibly occult or small hernia into its abnormal channel and more clearly demonstrate its presence. Herniography can only diagnose hernias, not other pathologies. MRI can diagnose adductor tendonitis, pubic osteitis, hip arthrosis, bursitis ileopectinea, and endometriosis amongst other conditions. If these ailments are part of the differential diagnosis, then MRI is the most suitable diagnostic tool<sup>120,121</sup>. CT can diagnose hernias as well and should be used when US is negative and MRI is not possible.

CE plus US is recommended as most suitable for the evaluation of patients suspected of having recurrent groin hernias. If diagnostic doubt exists after CE and US, MRI or CT should be considered. One prospective study and one retrospective case-control study, both of low quality, have addressed the issue of imaging for groin hernia recurrence<sup>122,123</sup>.

US, CT or MRI scans are helpful in identifying non-neuropathic causes of chronic groin pain by identifying mesh-related pathologies, recurrent hernias and occasionally neuromas<sup>124</sup>. A tailored, thoughtful approach to imaging is required since each of these imaging modalities possesses certain strengths and weaknesses and is not equally suited to diagnose all the listed conditions.

The use of US-guided nerve blocks is helpful in diagnosing chronic pain after surgery. A prospective cohort study described that the US-guided transversus abdominis plane block provided better pain diagnosis and control than blind ilio-hypogastric nerve block after inguinal

hernia repair<sup>125</sup>. Considering the much higher number of patients (n=273) compared to a randomized controlled trial with 24 included patients the quality rating of this PCS could be determined as “moderate”<sup>126</sup>. In another publication, the authors renounced the use of imaging as a helpful way to diagnose postoperative inguinal pain<sup>106</sup>. In short, it seems that US-guided nerve blocks are helpful in pinpointing the cause of chronic pain after groin hernia repair. Due to a lack of new studies and conflicting results in the available literature, the evidence supporting our recommendation on this KQ is considered “weak”.

## Chapter 4 Groin hernia classification

D. Cuccurullo and G. Campanelli

### Introduction

In day-to-day surgical practice a classification system for groin hernias is seldom used other than to describe hernia types in general terms (lateral/indirect, medial/direct, recurrent, and femoral). However, a consensus classification system is needed in order to perform research, tailor treatments to hernia types, and perform quality audits. Presently it is uncertain which hernia classification system is most suited to achieving this purpose.

### Key Question

**KQ04.a** Is a groin hernia classification system necessary, and if so, which classification system is most appropriate?

### Recommendation

<b>Recommendation</b>	Use of the EHS classification system for inguinal hernias is suggested for the purposes of performing research, tailoring treatments and performing quality audits.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Weak</b>
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### Evidence in Literature

The 2009 EHS guidelines recommended that the EHS classification system be used<sup>3</sup>. A 2015 literature review failed to reveal new proposed classification systems or new evidence on the value of the EHS system<sup>127</sup>. However, it is the opinion of the HerniaSurge members that one uniform system be adopted.

For inguinal hernia repairs, it is increasingly clear that surgeons tailor techniques to suit various patients and different hernia types. It is also necessary to compare results across different techniques and perform medical audits. More hernia registries are recommended and will require

that a consensus classification system be adopted. However, for now there is no consensus amongst general surgeons or hernia specialists on a preferred system.

The primary purpose of any disease classification system is to allow for severity stratification so that reasonable comparisons can be made between treatment strategies<sup>127</sup>. Additionally, a classification system must be simple and easy to use. Given the multiplicity of operative techniques and approaches for groin hernia repair it appears that no one classification system can satisfy all presently. However, an expert panel analyzed the known systems to date (Nyhus, Gilbert, Rutkow, Schumpelick, Harkins, Casten Halverson, McVay, Lichtenstein, Bendavid, Stoppa, Alexandre and Zollinger) and developed the EHS system by consensus<sup>127-134</sup>. HerniaSurge suggests this system be used since it fulfills most requirements and is relatively simple to use.

The EHS-system was not developed to classify hernia types preoperatively. This is a disadvantage. It is suggested that complex cases be managed by hernia experts. A classification to inform decision making about these complex cases would be helpful. However, many complex cases are easy to describe and don't require further classification (e.g. multiple recurrences and chronic pain).

EHS groin classification system	Primary / Recurrent				
	0	1	2	3	X
Lateral (L)					
Medial (M)					
Femoral (F)					

For now, the classification system for groin hernias is mired in some controversy and disagreement. However, the best available evidence and expert opinion supports the adoption of the EHS-system as classification system refinements evolve.

## Chapter 5 Indications - Treatment Options for Symptomatic and Asymptomatic Patients

B.J. van den Heuvel, A.R. Wijsmuller and R.J. Fitzgibbons

### Introduction

Approximately one-third of inguinal hernia (IH) patients are asymptomatic<sup>135</sup>. But, until recently, IH management involved surgical repair regardless of the presence of symptoms. The rationale being that surgery for asymptomatic IHs prevents hernia complications (incarceration or strangulation). Surgical management was also recommended for asymptomatic IHs because it was considered safe, effective, and associated with low morbidity. However, until recently, the natural history of untreated IHs—especially the incidence of complications—was unknown. Current literature now suggests the possibility of surgical overtreatment of men with asymptomatic IHs. Also, the morbidity of inguinal herniorrhaphy has been re-evaluated over the last two decades and current evidence suggests that the incidence of chronic post-herniorrhaphy pain is much higher than previously realized<sup>136</sup>.

Inguinal herniorrhaphy is one of the most common operations performed by general surgeons. Therefore, considering the number of IH repairs performed worldwide annually, the consequences of overtreatment are significant. This has spurred recent studies to evaluate a watchful waiting strategy in men with asymptomatic IHs<sup>137,138</sup>. A critical appraisal of these studies and previous assumptions is presented.

Based on the current literature, it is not possible to determine if a watchful waiting management strategy is safe for symptomatic men with IHs. Similarly, it is impossible to determine the hernia complication rate (strangulation or bowel obstruction) in symptomatic patients. Additionally, watchful waiting raises ethical issues about observing symptomatic patients.

### Key questions

**KQ05.a** Is a management strategy of watchful waiting safe for men with symptomatic inguinal hernias?

**KQ05.b** What is the risk of a hernia complication (strangulation or bowel obstruction) in this population?

**KQ05.c** Is a management strategy of watchful waiting safe for men with asymptomatic inguinal hernias?

**KQ05.d** What is the risk of a hernia complication (strangulation or bowel obstruction) in this population?



**KQ05.e** Are emergent inguinal herniorrhaphies associated with higher morbidity and mortality?

**KQ05.f** What is the crossover rate from watchful waiting to surgery?

### Statements and Recommendations

Statement	There is a low complication risk (incarceration or strangulation) in asymptomatic or <b>minimally symptomatic</b> men with inguinal hernias.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
Statement	Emergent repair of incarcerated or strangulated inguinal hernias in men is associated with higher morbidity and mortality compared with elective repair in men with <b>symptomatic</b> inguinal hernias.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
Statement	The crossover rate to surgery in men with <b>minimal symptomatic</b> inguinal hernias is high due to the development to symptoms, mostly pain.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
Statement	There is no evidence to support watchful waiting as a management strategy in men with <b>symptomatic</b> inguinal hernias. No data exist on the risk of incarceration or strangulation in this population.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Statement	Most men with <b>minimally symptomatic or asymptomatic</b> inguinal hernias will develop symptoms and require surgery.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
Recommendation	Although most patients will develop symptoms and need surgery, watchful waiting for <b>minimal or asymptomatic</b> inguinal hernias is safe since the risk of hernia complications is low and can be recommended.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Strong
Recommendation	Discussions with patients about timing of hernia repair are recommended to involve attention to social environment, occupation and overall health. The lower morbidity of elective surgery has to be weighed against the higher morbidity of emergency surgery.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *upgraded

## Evidence in Literature

The literature search on this topic yielded six randomized controlled trials (RCTs), two systematic reviews and three cohort-controlled studies. Two study groups produced all six RCTs<sup>137,138</sup>.

A 2006 trial of 720 men with minimally symptomatic or asymptomatic IHs randomized subjects to either primary surgery or watchful waiting (WW)<sup>137</sup>. Primary outcomes were pain interfering with normal activities and change in physical function as measured by the physical component score of the SF-36 at two years. Secondary outcomes included complications, and patient-reported pain, functional status, activity levels and satisfaction. Pain interfering with daily activity occurred in 5.1% of the WW group and 2.2% in the primary surgery group at two years ( $p=0.52$ ). SF-36 improvement from baseline was seen in both groups. One hernia incarceration occurred within the two-year minimum follow-up period and another occurred after 4.5 years (relative risk of 1.8 per 1,000 patient years). The crossover rates were high for both groups. At two years, 17% crossed over from surgery to WW and 23% from WW to surgery. A WW strategy was deemed safe and acceptable since acute incarcerations rarely occurred. A secondary analysis found that those who developed symptoms had no greater risk of operative complications or recurrence than those undergoing prophylactic hernia repairs.

A cost-effectiveness analysis was performed on the groups, calculating both costs and quality-adjusted life-years (QALYs)<sup>139</sup>. At two years, those in the surgery group had a \$1,831 higher mean cost per patient when compared with WW group subjects. The cost per additional QALY in the surgery group was \$59,065. WW was judged to be a cost-effective management option for men with minimal or absent hernia symptoms.

Seven years later the groups were restudied<sup>2</sup>. Crossover rates, crossover reasons and time to crossover were investigated. The crossover rate from WW to surgery was 50% at 7.3 years from randomization. Median crossover time was 3.7 years in men over 65 and 8.3 years in those 65 and younger ( $p=0.001$ ). The estimated crossover rate at ten years was 68% using Kaplan-Meier analysis. The primary reason for crossover was pain. When patients over 65 at time of original study enrollment were analyzed, the estimated ten-year crossover rate was 79.4%. This compares with a 62% ten-year crossover estimate for those 65 or younger at enrollment. In the seven-year follow-up only three men (2.4%) underwent surgery for a hernia accident. There was no mortality. The incidence of hernia complications for the entire cohort was 0.2 per 100 person-years. These studies support the idea that men with IHs and minimal or absent symptoms should be counseled that although WW is safe, symptoms will likely progress and an operation may be needed. A follow-up cost analysis has yet to be reported.

Another 2006 study randomized 160 men over the age of 55 with asymptomatic IHs to either WW (80 patients) or surgery (80 patients)<sup>138</sup>. The primary outcome was pain at one year as measured by the SF-36. Cost was a secondary outcome. At six months, improvement—in most SF-36 dimensions—was observed in the surgery group compared with the WW group. This effect had dissipated at 12 months and there were no significant inter-group differences in visual analogue pain scores at rest or with activity. Analgesic use between groups did not differ. The only notable inter-group difference at 12 months was in a single SF-36 item indicating perceived change in health. The one-year crossover rate from surgery to WW was 10% and 19% from WW to surgery. A single hernia incarceration occurred at 574 days. Primary surgical repair added 407.9 GBP in costs per patient (approximately \$591 US).

Long-term follow-up data were published in 2011<sup>140</sup>. At five years, 54% had crossed over from WW to surgery and an estimated 72% crossed over at 7.5 years. The most common crossover reason was pain. The estimated median time between randomization and crossover was 4.6 years. In 7.5 years, two patients required emergent hernia repair. The study's authors concluded that a WW strategy is of little value since the majority of WW patients will require surgery in the near term.

Two systematic reviews have appraised primary repair versus WW for minimally symptomatic or asymptomatic IHs in men<sup>141,142</sup>. Both reviews included mostly observational studies and pooled data on morbidity and mortality. Morbidity and mortality after elective repair was 8% and 0.2-0.5% respectively, versus 32% and 4-5.5% following emergent repair (a 10- to 20-fold increase in mortality). Risk factors for the observed increased morbidity and mortality include: age greater than 49 years, symptom duration, the presence of a femoral hernia, ASA class over two and nonviable bowel. Incarceration/strangulation risk factors are: symptom duration, age and hernia site (femoral). However, the reviews acknowledge that the incarceration/strangulation risk is low and that watchful waiting may be justified in selected patients.

Notably, both systematic reviews were published prior to the long-term RCTs cited above demonstrating symptom development over time in most men with minimally symptomatic or asymptomatic IHs. Symptom development (primarily pain) will prompt surgery. While it is true that incarcerations rarely occur in the WW group and are associated with defined risk factors, morbidity and mortality rates increase alarmingly when an IH strangulates.

A 2014 study reported on clinical consequences after the inception of a watchful waiting strategy<sup>143</sup>. Regionally, a WW policy was instituted in the United Kingdom for those with asymptomatic IHs. Outcomes of approximately 1,000 patients before, and 1,000 patients after, the policy's inception were compared retrospectively. The period following the policy change saw a 59% rise in the incidence of emergent hernia repair (3.6% vs 5.5%). Emergent repair was also associated with significantly more adverse events (4.7% vs 18.5%). Mortality spiked from 0.1% to 5.4%. This however was a retrospective study and did not report on the prior histories of those requiring emergent herniorrhaphies. Therefore, conclusions should be made with caution.

## Discussion, Consensus and Clarification of Grading

The initial results of a WW strategy in men with asymptomatic or minimally symptomatic IHs were promising. Complications occurred uncommonly and WW seemed cost effective in the short term. However, a longer-term view revealed high crossover rates due to symptom development, mostly pain. Whether WW is ultimately cost effective remains to be determined.

Observational studies have shown that emergent herniorrhaphy is associated with increased morbidity and mortality. Unfortunately, it is not possible currently to accurately predict which WW patients will develop symptoms or suffer a hernia complication. This foreknowledge would of course allow more tailored management.

Because of the increased morbidity and mortality associated with emergent herniorrhaphy the expert group advises that each patient with an asymptomatic or minimally symptomatic inguinal hernia be informed about the expected natural history of their condition, the timing, and the risks of emergency hernia surgery. Although robust support for a WW strategy and timing of surgery is not to be found in the present medical literature the expert group has upgraded its recommendation on this subject. This is because patient health-related, life style and social factors should all influence the shared decision-making process leading up to hernia management.

## Chapter 6 Surgical Treatment of Inguinal Hernia

Th.J. Aufenacker, F. Berrevoet, R. Bittner, D.C. Chen, J. Conze, F. Kockerling, J.F. Kukleta, M. Miserez, M.C. Misra, M.P. Simons, H.M. Tran, S. Tumtavitikul

### Key questions

**KQ06.a** Which non mesh technique is the preferred repair method for inguinal hernias?

**KQ06.b** Which is the preferred repair method for inguinal hernias: Mesh or non-mesh?

**KQ06.c** Which is the preferred open mesh technique for inguinal hernias: Lichtenstein or other open flat mesh and gadgets via an anterior approach?

**KQ06.d** Which is preferred open mesh technique: Lichtenstein versus open pre-peritoneal?

**KQ06.e** Is TEP or TAPP the preferred laparo-endoscopic technique for inguinal hernias?

**KQ06.f** When considering recurrence, pain, learning curve, postoperative recovery and costs which is preferred technique for inguinal hernias: Best open mesh (Lichtenstein) or a laparo-endoscopic (TEP and TAPP) technique?

**KQ06.g** In males with unilateral primary inguinal hernias which is the preferred repair technique, laparo-endoscopic (TEP/TAPP) or open pre-peritoneal?

**KQ06.h** Which is the preferred technique in Bilateral hernia.

### **General introduction**

Choosing the best or most suitable groin hernia repair technique is a true challenge. The best operative technique should have the following attributes: low risk of complications (pain and recurrence), (relatively) easy to learn, fast recovery, reproducible results and cost effectiveness. The decision is also dependent upon many factors like: hernia characteristics, anesthesia type, the surgeon's preference, training, capabilities and logistics. The patient's wishes must be considered. There are cultural differences between surgeons, countries and regions. Emotions may play a role as well.

Accordingly, the HerniaSurge Group had some passionate discussions when developing this chapter. One single standard technique for all hernias does not exist (see also chapter 7 on individualization).

In most situations a mesh repair is preferred. However, a minority of surgeons hold the opinion that mesh use should be avoided as much as possible. There is an ongoing discussion concerning the results of specialist centres like The Lichtenstein Hernia Clinic and The Shouldice Hospital. There are low-resource settings where mesh cannot be afforded. There are high-volume laparo-endoscopic surgeons who passionately advocate a TEP or TAPP in almost all cases. There are gadgets (often expensive) used by surgeons who have been successful with them for many years. How then can one reconcile these opinions and conflicts?

Although accurate and recent facts are not available, in most countries the Lichtenstein repair is probably the first choice in a majority of cases. It is a very good technique but its outcomes may be bested by a more difficult technique like the TEP when early post-operative recovery and the aspects of chronic pain are considered. It is self-evident that a surgeon performing a technique and striving for optimal results should know the technique very well. Excellent training and a high caseload are the foundations of good surgery. This could imply that a Shouldice in The Shouldice Hospital, a Lichtenstein in The Lichtenstein Amid Hernia Clinic and for example a TAPP in the Marienhospital Stuttgart have comparable results.

When comparing the best Lichtenstein outcomes with the best TEP/TAPP it is noted that the differences are very small. It is challenging though when examining results reported in the literature because often the techniques being compared are not performed in a standardized manner by equally skilled and experienced surgeons. Therefore, this might not be true when comparing an average Lichtenstein to an average TEP/TAPP or Shouldice because of the former's lower complexity.

Applying research results to the approach for an individual patient is problematic as well. It is often far from clear whether the results of an RCT can be generalized to one's practice setting or patients within that setting.

In the European Guidelines, raw data were used to conclude that laparo-endoscopic and open repair were comparable in long-term follow-up of a minimum of 48 months<sup>3,144</sup>.

When reading this chapter, realize that potential bias exists, caused by: lack of a clear chronic pain definition, variations in duration of chronic pain, age differences for the risk of chronic pain, lack of a generally-agreed-upon classification system describing the type of hernias, differences in level of surgical expertise, differences in case load needed to maintain a certain technique, safety issues regarding training of the surgeons/residents in the world in difficult techniques like the TEP and TAPP, and costs of procedures, amongst others. In fact, all these factors must be considered when studying the evidence presented in the different chapters.

The chapters were researched and written by different teams but the statements and recommendations were agreed upon by the whole HerniaSurge Group. Many lively discussions during the meetings and via email led to an internet consensus vote. There are recommendations that have been upgraded or downgraded. The support for these decisions is at the end of each chapter.

#### **KQ06.a** Which non mesh technique is the preferred repair method for inguinal hernias?

J. Conze, M.P. Simons and M. Miserez

### **Introduction**

The 2009 European guidelines opined that the Shouldice inguinal hernia repair was the best non-mesh technique<sup>3</sup>. Since then, no studies have offered new evidence concerning a comparison between non-mesh techniques. Questions remain concerning the value of a non-mesh technique in certain cases like indirect hernias (EHS L1 and L2) in young male patients. There are also regions (low resource countries in particular) where mesh is not available and surgeons must use the best non-mesh technique. Also some patients refuse a mesh implant. Which non-mesh technique is best therefore remains an important question.

### **Recommendation**

<b>Recommendation</b>	The Shouldice technique has lower recurrence rates than other suture repairs and is recommended in non-mesh inguinal hernia repair.	☒☒☒☐	<b>Strong</b> <b>*upgraded</b>
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### **Evidence in Literature**

*Systematic Review Cochrane 2012*

A 2012 review covered all prior RCTs (until September 2011) concerning results of the Shouldice technique versus other open techniques (mesh and non-mesh)<sup>144</sup>. Eight RCTs with 2,865 patients are contained, comparing mesh versus non-mesh IH repair. Most of these trials had inadequate randomization methods, did not mention dropouts and did not blind patients and surgeons to the technique used. Recurrence rate was a primary outcome in all and pain could only be analyzed in three trials. Pain definitions and measurements were not standardized. Studies were heterogeneous, with concerns that techniques were not standardized. The results show that in Shouldice versus other non-mesh (8 studies) the recurrence rate was lower in Shouldice (OR 0.62, 95% CI 0.45-0.85 NNH 40). Six studies reported an OR in favor of the Shouldice technique. One included study reported the most data and its weight in the analysis was 59.56%<sup>145</sup>. The results reflect different degrees of surgeon's familiarity with the techniques, making it impossible to eliminate the "handcraft" variable from surgical trials. Shouldice also results in less chronic pain (OR 0.3; 95% CI 0.4-1.22) and lower rates of hematoma formation (OR 0.84; 95% CI 0.63-1.13) but slightly higher infection rates (OR 1.34; 95% CI 0.7-2.54). It is more time consuming and leads to a slightly increased hospital stay (WMD 0.25; 95% CI 0.01-0.49). In their discussion, the authors conclude that the review is flawed by: the inclusion of low quality RCTs, non-blinded outcomes assessments, lack of external validity by patient selection (only healthy patients were included), high lost-to-follow-up rates, no patient-oriented outcomes and the above-mentioned potential bias. Nevertheless, the large number of patients and consistent results do make the results useable in clinical practice. Since this systematic review was done, no new RCT comparing Shouldice with other non-mesh techniques has been published<sup>144</sup>. The level of the review with RCTs is downgraded to moderate. The level of recommendation is upgraded to strong by HerniaSurge because the Shouldice technique is the best-studied and researched non-mesh method with an anatomically sound approach.

### *Other Non-mesh Techniques*

A 2012 RCT, in which 208 patients were randomized, described the Desarda technique compared with a Lichtenstein technique<sup>146</sup>. Follow-up at 36 months found recurrence rates in each group of 1.9% and no significant differences in pain. As this is a new technique with some non-randomized studies showing promising results, it is worthy of mention in the guidelines. The level of the RCT is moderate and no recommendations can be formulated. The Desarda technique needs further investigation.

### *Large Database Studies*

The large databases from Denmark and Sweden indicate results of non-mesh techniques but cannot differentiate between different techniques so conclusions cannot be made concerning the quality of the Shouldice technique<sup>147</sup>. In a 2004 questionnaire study,<sup>11,147,148</sup> using results from the Danish database, chronic pain was more common after primary IH repair in young males, but there was no difference in pain when comparing Lichtenstein with non-mesh Marcy and Shouldice repairs. The databases conclude less recurrences after mesh repair but not at the cost of more chronic pain.

### *Guidelines*

The European Guidelines concluded that the Shouldice hernia repair technique is the best non-mesh repair method with a 1B level of evidence<sup>3</sup>.

### Discussion, Consensus and Grading Clarification

When considering the results from the systematic review, large databases and guideline conclusions, we conclude that Shouldice is superior to other non-mesh techniques especially when considering recurrence rates. In the systematic review the level of evidence was downgraded to moderate. But combining all the evidence, and after consensus by HerniaSurge, we concluded that a recommendation, upgraded to “strong” was supportable. In other words, in non-mesh repair, perform a Shouldice.

Although no studies exist on a comparison of the learning curves of the different non-mesh techniques, the HerniaSurge committee agrees that the Shouldice technique is not easy to learn. In The Shouldice Hospital, surgeons are only considered qualified after 300 cases! It is well known that in many countries a modified Bassini is performed simply because it requires less anatomy knowledge and is a safer technique.

Another matter is a discussion concerning the results of only sac resection and high ligation in young adults. HerniaSurge is of the opinion that this issue needs further research. We are unable to formulate a statement on it presently.


### **KQ06.b** Which is the preferred repair method for inguinal hernias: Mesh or non-mesh?

M.P. Simons, J. Conze and M. Miserez

#### Introduction

The 2009 European Guidelines concluded that all male adults over the age of 30 with a symptomatic IH should be operated on using a mesh-based technique (grade A)<sup>3</sup>. In most countries, the use of mesh has been accepted by the majority of surgeons as the best approach to decrease risk of recurrence. There are concerns about mesh causing more chronic pain. Other reasons not to use mesh include: higher cost or non-availability of meshes in low resource settings, lack of surgical expertise with mesh, and patient refusal of a mesh repair. It remains to be seen whether a mesh-based technique is indicated in all cases (see also chapter 7 on individualization).

### Statement and Recommendations

<b>Recommendation</b>	A mesh-based repair technique is recommended for patients with symptomatic inguinal hernias.		<b>Strong *upgraded</b>
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<i>Statement</i>	Whether a non-mesh technique is an alternative for mesh-based techniques in individual cases (e.g. young males with lateral hernia L1) is unknown and requires further study.	☒☒☐☐	
<i>Recommendation</i>	The use open non-mesh repair in specific patients or types (e.g. young males with lateral hernia L1) of inguinal hernia to replace the Lichtenstein technique should only be performed in research settings.	☒☒☐☐	Strong *upgraded

## Evidence in Literature

### *Systematic Review Cochrane 2012*

A 2012 systematic review covered all prior RCTs (until September 2011) concerning results of Shouldice versus other open techniques<sup>144</sup>. The review contains 6 RCTs including 1,565 patients and compared Shouldice versus open mesh (Lichtenstein in all studies except one with plug and patch) for IH repair. The overall RCT quality is low. Recurrence rates were the primary outcome. Pain definitions and measurements were not standardized. Studies were heterogeneous. There are concerns that techniques were not standardized and no classification was applied.

The results show, that in Shouldice versus mesh Lichtenstein, recurrence rate were higher in Shouldice (5 studies) (OR 3.65, 95% 1.79-7.47, NNH 36). Although not the primary endpoint in most trials, there were no significant differences between Shouldice and Lichtenstein for postoperative stay, chronic pain, seroma/hematoma and wound infection, but operative time was shorter for mesh repair (WMD 9.64 min; 95% CI 6.96-12.32).

The authors concluded that the review is flawed by low quality RCTs, non-blinded outcomes assessment, external validity concerns due to patient selection (generally healthy patients were studied), high lost-to-follow-up rates, lack of patient-oriented outcomes and the above mentioned potential bias concerning surgical technique. Nevertheless, the large number of patients and consistent results do make the results reliable.

### *Other RCTs since the Systematic Review*

Since September 2011, three RCTs have been published describing a non-mesh versus mesh repair but they were excluded because they either did not include Shouldice repairs<sup>149-151</sup>, Lichtenstein repairs<sup>149,152</sup>, or had a very short follow-up<sup>150-152</sup>.

One 2012 RCT, in which 208 patients were randomized, compared the Desarda technique with a Lichtenstein technique. At 36-month follow-up, the recurrence rate in each group was 1.9% and no significant differences in pain were found. The Desarda technique is new and the subject of

some non-randomized studies showing promising results but the technique needs further investigation. The 2012 RCT is graded as moderate. No recommendations about its use can be made at this point.

### *Large Database Studies*

Two publications from the Danish Hernia Database describe recurrence after 96 months following open non-mesh versus Lichtenstein. The recurrence rate after open non-mesh repair was 8% versus 3% for Lichtenstein<sup>11,153,154</sup>. These studies are biased since not only Shouldice was used in the non-mesh group (only 13% of all suture repairs) and only reflect reoperation (rather than recurrence) rates. They do offer insights though about outcomes in a general population being treated by general surgeons (see chapter 25 concerning the value of database studies). A 2004 questionnaire study of the Danish database found that chronic pain occurred more commonly after primary IH repair in young males. But, no differences in pain occurred when comparing Lichtenstein with Marcy and Shouldice non-mesh repair techniques. The database studies also found fewer recurrences after mesh repair.

### *Guidelines*

The European Guidelines concluded that all male adults over the age of 30 years with a symptomatic IH should be operated on using a mesh technique (grade A)<sup>3</sup>.

### *Cohort studies*

There is lower level evidence that the Shouldice technique has a recurrence rate of less than 2% especially when performed in high-volume expert settings like the Shouldice Hospital<sup>155</sup>. These data come primarily from expert centers like the Shouldice Hospital. Often the studies suffer from inadequate follow-up and there is patient selection bias in some. This gives rise to a dispute between open non-mesh surgeons and surgeons advocating mesh repair on the true value of the Shouldice repair. Resolution is unlikely unless an RCT is performed with adequate methods truly comparing techniques by surgeons qualified and experienced in both approaches. This might be possible using large databases provided identification of Shouldice technique is done. It is clear from all high-level studies though that in general practice, mesh is superior to non-mesh especially when measuring recurrence rate. It absolutely recommended that studies be performed into the value of Shouldice in young male patients with lateral (L1) inguinal hernia. Furthermore, it is unknown whether a sac resection (herniotomy) has comparable results to Shouldice in these patient groups.

## **Discussion, Consensus and Grading Clarification**

Mesh-based techniques compared to non-mesh techniques have a lower recurrence rate and an equal risk of post-operative pain. Despite the mentioned limitations of the 2012 review, the large number of patients and consistent results do make available findings reliable and useable in practice. There is no indication that mesh causes more chronic pain. It remains to be seen whether

a mesh-based technique is indicated in all cases such as small lateral hernias (EHS L1 and L2) (see chapter 7 on individualization).

Also the impact of surgical experience and whether the Shouldice technique in specialized hands can be comparable to mesh-based techniques is unclear. Specialized centers have not published their results in a reliable manner. Many cohort studies contain bias and thus lack external validity.

Although the level of evidence seems only moderate, by consensus in HerniaSurge the recommendation to use a mesh-based technique in inguinal hernia repair is upgraded to “strong.”

**KQ06.c** Which is the preferred open mesh technique for inguinal hernias: Lichtenstein or other open flat mesh and gadgets via an anterior approach?

M. Miserez, J. Conze and M. Simons

## Introduction

The Lichtenstein technique with the onlay placement of a flat mesh is the criterion standard in open IH repair<sup>156</sup>. Many alternatives to the original Lichtenstein technique have been described. The plug-and-patch (or mesh-plug) technique was the first<sup>157</sup>, followed by the Trabucco technique<sup>158</sup> and the Prolene® Hernia System (PHS)<sup>159</sup>.

In the Trabucco technique, a polypropylene plug is combined with a semi-rigid flat pre-shaped polypropylene mesh. Neither implant is fixed. The spermatic cord is placed subcutaneously. At the time of the first EHS guidelines on the treatment of IH in adults, no long-term comparative follow-up data were available on any of these techniques<sup>3</sup>, but this changed at the time of the update with level 1 studies of the EHS guidelines. In addition, self-gripping meshes have been designed; this, in an attempt to reduce or abandon the need for traumatic mesh fixation in Lichtenstein repair and decrease the risk for acute and chronic pain.

## Statements and Recommendations

*Statement*

The recurrence rate and postoperative chronic pain are comparable between plug-and-patch/ PHS and the Lichtenstein technique.

☒ ☒ ☐ ☐

*Statement*

Self-gripping meshes do not provide any benefit in the short- and medium-term versus the Lichtenstein technique except a somewhat decreased operative time.

☒ ☒ ☐ ☐

<b>Recommendation</b>	Despite comparable results, the plug-and-patch and PHS are not recommended because of the excessive use of foreign material, the need to enter both the posterior and anterior plane and the additional cost.	⊗⊗□□	<b>Strong</b> *upgraded
<b>Recommendation</b>	The use of other meshes or gadgets to replace the standard flat mesh in the Lichtenstein technique is currently not recommended.	⊗⊗□□	<b>Strong</b> *upgraded

## Evidence in Literature

### *Plug-and-Patch*

The recent EHS guidelines update<sup>4</sup> with level 1 studies, included data on the comparison between plug-and-patch versus Lichtenstein from two meta-analyses of seven RCTs<sup>160,161</sup>. These showed shorter operative times for the plug-and-patch (by 5-10 minutes), but otherwise comparable outcomes in the short- and long-term (follow-up ranging from 0.5 to 73 months).

Long-term follow-up data from two of the RCTs were published in 2014. The first study used a questionnaire to assess recurrence rates and chronic pain after a median follow-up of 7.6 years (n=180, 81% follow-up rate)<sup>162</sup>. Recurrence rates for Lichtenstein and plug-and-patch were 5.6% and 9.9% respectively (p=0.770). Moderate or severe pain was reported in 5.6% and 5.5% respectively (p=0.785). The second study—which also included recurrent hernias—evaluated patients by means of physical examination after a 6.5-year median follow-up and had similar findings (n=528, 76% follow-up rate)<sup>163</sup>. Recurrence rates for Lichtenstein and plug-and-patch were 8.1% and 7.8% respectively (OR 0.92 n.s.) and chronic persistent pain (VAS>3) XX and YY. More reoperations occurred in the Lichtenstein group (OR 0.43, p=0.016).

### *Prolene® Hernia System (PHS)*

At the time of the EHS update, two meta-analyses of six RCTs were published comparing PHS and Lichtenstein (follow-up ranging from 12 to 48 months)<sup>160,164</sup>. One long-term follow-up study (5-year follow-up) was included in the meta-analyses<sup>165</sup>. No differences in recurrence or chronic pain were found. The data on operative times and perioperative complications were contradictory in the meta-analyses, although no differences were seen for postoperative wound hematoma formation or infection in either.

A 2014 long-term outcome study (mean follow-up of 7.6 years) also include a PHS arm and these data are reported below<sup>162</sup>, confirming earlier results. The recurrence rates for Lichtenstein and PHS were 5.6% and 3.3% respectively (p=0.770). The incidence of chronic pain (moderate or severe) was 5.6% and 6.7% respectively (p=0.785).

A large pore version of the PHS, the Ultrapro® Hernia System (UHS), was launched recently. One RCT compares Lichtenstein and the UHS<sup>166</sup>. Another RCT compared the plug-and-patch technique with a 4D Dome® device in 95 patients<sup>167</sup>. The “dome device” consists of a largely resorbable dome-shaped plug (90% poly-L-lactic acid and 10% polypropylene) associated with a

flat lightweight polypropylene mesh. Because of poor methodological quality (according to SIGN criteria), neither paper is further discussed here.

### *Trabucco*

One RCT compared the Lichtenstein with the Trabucco technique in 108 patients under local anesthesia<sup>168</sup>. The Trabucco technique was an average of 10 minutes faster vs. Lichtenstein ( $p=0.04$ ). There were no differences in postoperative pain (primary outcome) or groin discomfort at six months. At an average follow-up of eight years (only telephone follow-up after one year), there were no recurrent hernias.

### *Self-gripping Mesh*

The first study on the use of the self-gripping Parietene Progrid© mesh (large pore polypropylene (pp) with resorbable polylactic acid micro grips) found less pain on the first postoperative day when compared with the use of another large-pore non-gripping polypropylene mesh<sup>169</sup>. Subsequently, four other RCTs comparing self-fixating large-pore mesh vs suture fixation in Lichtenstein have been published up to 2013<sup>170–173</sup>. These studies have been evaluated in five different meta-analyses, all published in 2013 and 2014 in different journals<sup>174–178</sup>. All confirm no difference in acute or chronic pain or recurrence rates.

Three additional RCTs were published in 2014<sup>179–181</sup>, and another two were published with long-term data from an RCT published earlier<sup>182,183</sup>. All confirmed comparable recurrence rates and acute and chronic pain incidence in both groups. The self-fixation mesh is likely to be more expensive than standard fixation, but the operative time was shorter in the Progrid© group (by a range of 1 to 12 minutes).

Since only data on medium-term follow-up are available (range 6-24 months), we advise the authors of the previously mentioned trial data to follow-up their patients at three to five years and publish their updated results on chronic pain and recurrence rates.

## **Discussion, Consensus and Grading Clarification**

Plug-and-patch and PHS are acceptable treatments for primary IHs but have no benefit vs. the Lichtenstein technique, except a somewhat shorter operative time for the plug-and-patch technique. However, both the anterior and posterior compartment are entered and scarred, making a subsequent repair for recurrence more difficult. Also, the amount of foreign material is higher than for a simple flat mesh. And—in the case of a combined hernia—the placement strategy for the device or plug is not standardized. The additional cost of the device needs to be taken into account as does the small chance of mesh migration/erosion with the use of plugs. Therefore, the Lichtenstein technique with a flat mesh is considered to be superior. See also chapter 10 on mesh in which the problems of mesh plug erosion and migration are described.

The same is true for self-gripping mesh, although only medium-term data are available. Self-gripping mesh is an acceptable form of treatment for primary IHs but has no benefit vs. the

Lichtenstein technique, again except a somewhat shorter operative time. Here also, the device's additional cost must be considered.

Based on the information currently available and presented above, the use of other meshes or gadgets to replace the standard flat mesh in the Lichtenstein technique is currently not recommended.

**KQ06.d** Which is the preferred open mesh technique for inguinal hernias: Lichtenstein or any open pre-peritoneal technique?

F. Berrevoet, Th. Aufenacker and S. Tumtavitikul

## Introduction

Open pre-peritoneal techniques have gained more attention in the repair of IHs during the last two decades as a result of technical and commercial considerations. Surgeons should understand that “open pre-peritoneal techniques” include several different approaches, including: the transinguinal pre-peritoneal repair described by Pélissier (TIPP)<sup>184</sup>, the posterior Kugel technique<sup>185</sup>, transrectus pre-peritoneal approach (TREPP)<sup>186</sup>, Onstep approach<sup>187</sup>, Ugahary technique<sup>188</sup>, Wantz technique<sup>189</sup> and Rives' technique<sup>190</sup> for anterior pre-peritoneal repair. Note that TIPP, Onstep, and Rives' techniques approach the pre-peritoneal space through an anterior dissection opening the inguinal canal. Kugel, TREPP, Ugahary and Wantz use a posterior approach to open repair without entering the inguinal canal anteriorly.

Onstep is comparable with the PHS/UHS system, although there is only one mesh layer reinforcing the medial side pre-peritoneally.

There are no data comparing the open pre-peritoneal techniques with each other, so no recommendation can be made about the preferred open pre-peritoneal technique. However, we are able to make the following statements and recommendations based on limited data about pre-peritoneal techniques.

## Statements and Recommendation

<i>Statement</i>	Open pre-peritoneal mesh repairs may, in the short term (one year), result in less postoperative and chronic pain and faster recovery. It must however be considered that some of these approaches use both anterior and posterior anatomical planes.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Use of mesh devices results in increased costs and there are possible issues with the memory ring in some.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

<b>Statement</b>	In open surgery there is insufficient evidence to recommend a pre-peritoneal mesh repair over Lichtenstein repair.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<b>Recommendation</b>	The use of open pre-peritoneal mesh techniques to replace the standard flat mesh in the Lichtenstein technique is suggested to only be performed in research settings.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Weak

## Evidence in Literature

Two meta-analyses, one systematic review and three RCTs were identified out of 596 publications as suitable for inclusion and analysis below.

### *Cochrane Systematic Review 2009*

A 2009 Cochrane Systematic Review included three eligible trials with 569 patients<sup>191</sup>. Due to methodological limitations in the three trials considerable variations were found in acute pain (risk range 38.67% to 96.51%) and chronic pain (risk range 7.83% to 40.47%) across control groups. Two trials involving 322 patients found less chronic pain after pre-peritoneal repair (relative risk 0.18). These same two trials also found less acute pain (relative risk 0.17). One study of 247 patients found more chronic pain after pre-peritoneal repair (relative risk 1.17). This study reported that acute pain was nearly omnipresent and thus comparable in both intervention arms (relative risk 0.997, NNT 333). Early and late hernia recurrence rates were similar across the studies. Conflicting results were reported for other early outcomes like infection and hematoma formation.

Both pre-peritoneal and Lichtenstein repairs were seen as reasonable approaches since they resulted in similarly low hernia recurrence rates. There is some evidence that pre-peritoneal repairs cause less, or at least comparable, acute and chronic pain when compared with the Lichtenstein procedure. However, the Systematic Review authors emphasized the need for homogeneous high-quality randomized trials comparing elective pre-peritoneal IH repair techniques with the Lichtenstein repair to assess chronic pain incidence.

### *Meta-analysis 2013*

A 2013 meta-analysis of 12 RCTs involving 1,437 patients considered open transinguinal pre-peritoneal repair (TIPP) versus Lichtenstein in both primary and recurrent IHs<sup>192</sup>. Unpublished data were used and data was extracted from a four-arm study using only two relevant arms. The “TIPP technique” was considered to be the Kugel approach, the actual TIPP technique and the Rives’ technique. The meta-analysis concluded that the “TIPP repair” was associated with a reduced risk of chronic groin pain (RR, 0.48; 95% CI, 0.26, 0.89;  $z = 2.33$ ;  $p < 0.02$ ) without increasing the incidence of inguinal hernia recurrence (RR, 0.18; 95% CI, 0.36, 1.83;  $z = 0.51$ ;  $p = 0.61$ ). It was also concluded that—accounting for the significant heterogeneity amongst the

different trials—the “TIPP technique” is comparable with the Lichtenstein repair in terms of hernia recurrence risk, postoperative complications, operation duration and postoperative pain intensity.

A second meta-analysis published in 2014, was judged to be of low methodological quality according to SIGN criteria and was withdrawn from analysis<sup>193</sup>.

### *RCT 2012*

A 2012 study of TIPP versus Lichtenstein randomized 301 patients and used chronic postoperative pain at one year as the primary outcome measure<sup>194</sup>. Patients and outcome assessors were blinded. Significantly fewer TIPP patients had continuous chronic pain, 3.5% versus 12.9% in the Lichtenstein group ( $p=0.004$ ). No significant intergroup differences were noted for other severe adverse events, including recurrence.

Another RCT, comparing Kugel versus Lichtenstein repair, was withdrawn from analysis due to low methodological quality by SIGN criteria<sup>195</sup>. The same is true for another RCT comparing TIPP versus Lichtenstein repair<sup>196</sup>.

### **Discussion, Consensus and Grading Clarification**

From the summed evidence, it can be concluded that open pre-peritoneal repairs seem as effective as the Lichtenstein repair in terms of recurrence and may possibly result in less postoperative pain and faster recovery. However, the caveat is that mainly the anterior transinguinal pre-peritoneal technique (TIPP) and the posterior pre-peritoneal technique as described by Kugel have been compared to the Lichtenstein repair. This caution is reinforced in the 2009 Guidelines of the Hernia Society and its 2014 update<sup>3,4</sup>. The various other open pre-peritoneal techniques have not been sufficiently studied to differentiate them one from another.

Concerns about these surgical techniques may exist regarding both cost and long-term safety for some of these mesh devices. For the Kugel mesh there is an abundant amount of foreign material present. Problems with the initial recoil ring resulted in pain and even bowel perforation. The recent version of this mesh type now contains a resorbable memory ring. This being said, whether it is TIPP, Kugel, TREPP or others, the mesh choice is not strictly connected to the applied technique.

Mesh devices are more costly than flat meshes. However, a 2013 study found no differences in hospital costs between TIPP and Lichtenstein repairs. When productivity gains were included in the analysis, significant differences in cost favouring the TIPP modality were noted ( $p=0.037$ )<sup>197</sup>. Individual surgeons and healthcare systems may wish to consider this point, depending on practice setting and reimbursement systems.



HerniaSurge acknowledges the potential value of open pre-peritoneal mesh techniques. A need remains for learning curve studies and RCTs and registry studies with long-term follow-up to be able to make firmer conclusions.

## KQ06.e Is TEP or TAPP the preferred laparo-endoscopic technique?

Reinhard Bittner, Ferdinand Köckerling, Jan Kukleta, Sathien Tumtavitikul and Mahesh Misra

### Introduction

Trans Abdominal Pre-Peritoneal (TAPP) and Total Extra Peritoneal (TEP) differ although both techniques are in widespread use. In both, mesh is inserted in the pre-peritoneal plane but use different access to that plane. In TEP, a totally pre-peritoneal approach is used with or without the help of a dissection balloon. In TAPP a laparoscopy is performed. The approach difference confers a theoretical advantage favoring TAPP. The anatomy is easier to identify when starting with a laparoscopy and the type of hernia on the contralateral side can be identified before starting dissection. Studies comparing TAPP and TEP show similar complication rates—possibly caused by dissection and mesh placement in the pelvic floor—like: seroma, scrotal edema, cord swelling, testicular atrophy, urinary bladder injury, inguinal nerve lesions, chronic pain and recurrence. Access-related complication risk might differ. These are mainly due to the fact that in TAPP because of the transabdominal route the risk for visceral injuries is increased, but in TEP because of the total extraperitoneal route the risk for vascular lesions.

### Statements and Recommendations

<i>Statement</i>	TAPP and TEP have similar operative times, overall complication risks, postoperative acute and chronic pain incidence and recurrence rates.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Although very rare, there is a trend in TAPP for more visceral injuries.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Although very rare, there is a trend in TEP for more vascular injuries	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Although very low, in TAPP the frequency of port-site hernias is higher.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Although very low, in TEP the conversion rate is higher.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>

Statement	Similar costs may be incurred in TAPP and TEP.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	
Statement	TEP has a longer learning curve than TAPP.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Recommendation	In laparo-endoscopic inguinal hernia repair, TAPP and TEP have comparable outcomes; hence it is recommended that the choice of the technique should be based on the surgeon's skills, education and experience.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	Strong

## Evidence in Literature

### Systematic review

A qualitative systematic review of 71 TAPP and TEP studies showed no difference in acute pain intensity or duration<sup>198</sup>. The same is generally true for chronic pain, with six studies showing no difference<sup>199–204</sup> and two<sup>205,206</sup> slightly better outcomes after TAPP (1.15% vs. 3.03%<sup>206</sup>; 3.5% vs. 9%<sup>205</sup>).

### RCTs

Eleven RCTs were analyzed. All suffered from bias. A variety of confounding factors potentially impacting results were not mentioned or accounted for and were not identified by multivariate analyses. Most of the randomized studies lack statistical power<sup>68,207,208</sup>. The numbers of patients per intervention group were inadequate resulting in the risk of a type II error<sup>209–213</sup>. Methods of patient allocation to one of the two techniques were not clearly stated<sup>204,214,215</sup>. Surgeon's levels of experience with both techniques were not studied. In five of the studies, surgeons started laparoscopic hernia repair with TAPP, then, after gaining experience, switched to TEP. Thus the level of experience in laparoscopic surgery was not equivalent at the study's beginning<sup>208,216–219</sup>. The cited high early recurrence rates (>25%) and long operative times strongly suggest that the studied surgeons had not yet completed the learning curve<sup>204,212,213,218–220</sup>. Technique details (mesh types, fixation types) which could influence postoperative pain or recurrence were omitted<sup>68,201–203,205–207,209,210,213,214,216,219,221–223</sup>. Some of the studies employed overly small meshes (<10x15 cm) or mesh of different size for TAPP and TEP<sup>203,204,217–221</sup>. Finally, follow-up duration differed for the TAPP and TEP groups (24 to 42.5 months vs 9 to 28.8 months)<sup>207,209–214,216,221,224,225</sup>.

### Operation time, recurrence rate, pain, costs.

Due to the heterogeneity and weaknesses of the TAPP vs TEP studies, results varied greatly. In 22 comparisons, TAPP operative times varied from 34.5 minutes to 104.5 minutes (median of 57 minutes) and TEP operative times varied from 32.5 to 110 minutes (median of 62.3 minutes). In 24 comparisons, TAPP complication rates ranged from 1.23% to 49% (median of 11.4%) and TEP complication rates ranged from 1.3% to 50.3% (median 12.5%). In 23 comparisons, TAPP recurrence rates varied between 0% and 25% (median 2.3%) and TEP recurrence rates between 0% and 16.7% (median 0.6%). Interestingly, an analysis of the 1990-to-1998 literature (TAPP and TEP, 13 studies each) showed a TAPP recurrence rate of 1.33% and a TEP recurrence rate of

0.6%. In the 1999-to-2008 period (seven TAPP and eight TEP studies), recurrence rates dropped to 0.77% for TAPP and 0.54% for TEP, reflecting improved technical performance over time<sup>5,226</sup>.

#### *Large data base study*

A large population-based study in German hospitals found no differences in TAPP and TEP costs<sup>227</sup>. The most recently published meta-analysis of ten RCTs failed to show any significant differences in operative times, total complication rates, hospital length of stay, recovery time, pain, recurrence rates or costs between TAPP and TEP<sup>228</sup>.

#### *Guidelines*

Whereas the EHS-Guideline does not refer to any comparison between TAPP and TEP, both other guidelines (IEHS and EAES) report a similar result like described above.

### **Discussion, consensus and clarification of grading**

Only three of 29 RCTs and observational studies focused on primary, unilateral hernias in men<sup>211,229,230</sup>. In spite of all variations and limitations of most of the comparative studies, all eight meta-analyses and systematic reviews inclusive of these studies concluded that insufficient evidence exists to recommend the use of one technique over the other<sup>198,228,231–236</sup>. Each technique has different, very rare, but serious, complications associated with it. One registry study reported a lower TAPP complication rate<sup>215</sup>, while another reported a lower TEP complication rate<sup>237</sup>. Operative team ease and experience are important factors in the decision to use one technique preferentially<sup>225</sup>.

**KQ06.f** When considering recurrence, pain, learning curve, postoperative recovery and costs which is preferred technique for inguinal hernias: Best open mesh (Lichtenstein) or a laparo-endoscopic (TEP and TAPP) technique?

F. Köckerling, H. Tran and D. Chen

### **Introduction**

In the EHS guidelines, open Lichtenstein and laparo-endoscopic IH techniques (TEP/TAPP) are recommended as the best evidence-based options for repair of primary unilateral hernias provided the surgeon is sufficiently experienced in the specific procedure<sup>3,4</sup>.

The HerniaSurge committee thought it prudent to account for all important factors when considering recommendations on Lichtenstein and laparo-endoscopic techniques. It seems clear that when considering post-operative pain, recovery speed and chronic pain, the laparo-endoscopic techniques are superior. In TEP and TAPP expert hands, especially when performing high-volume surgery, those techniques are probably also cost effective and very safe. However, many of the studies in this area suffer from weakness such as: lack of clear endpoints in pain assessment, definitions, quality of the surgeon's technique, caseload per surgeon, and lack of hernia classification as to the different levels of risk for complications. Additionally, there is a well-documented difference in learning curve and initial costs favoring Lichtenstein.

In order to properly address the Key Question, all meta-analyses and RCTs must be excluded that compared laparo-endoscopic techniques with either, open techniques other than Lichtenstein, and/or those that enrolled patients other than males with primary unilateral IHs.

## Statements and Recommendations

<i>Statement</i>	When the surgeon has sufficient experience in the laparo-endoscopic techniques, comparable recurrence rates to Lichtenstein repair can be achieved.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	When the surgeon has sufficient experience in the technique, laparo-endoscopic techniques show advantages in terms of less early postoperative pain at rest and on exertion and less chronic pain when compared with Lichtenstein technique.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	When the surgeon has sufficient experience in the technique, laparo-endoscopic techniques do not take longer than Lichtenstein operations.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	With sufficient experience, no significant differences are observed in the perioperative complications needing reoperation between the laparo-endoscopic and Lichtenstein techniques.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	The direct operative costs for laparo-endoscopic inguinal hernia repair are higher. That difference decreases when the total community costs are taken into account and the surgeon has sufficient experience.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	The learning curve for laparo-endoscopic techniques (especially TEP) is longer than for Lichtenstein. There are rare but severe complications mainly described early in the learning curve. Therefore, it is imperative that laparo-endoscopic techniques be learned in a properly supervised manner.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>Recommendation</b>	For male patients with primary unilateral inguinal hernia, a laparo-endoscopic technique is recommended because	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <b>Strong</b>

of a lower postoperative pain incidence and a reduction in chronic pain incidence, provided that a surgeon with specific and sufficient resources is available. However, there are patient and hernia characteristics that warrant a Lichtenstein as first choice. (see chapter 7 on individualization)

\*upgraded

## Evidence in Literature

### *Systematic Reviews and Meta-analyses*

In meta-analyses from 1999, 2000, 2003 and 2012, TEP and TAPP are compared with all open procedures used for IH repair<sup>231,234,238,239</sup>. Only in a 2005 meta-analysis subgroup analysis were the TAPP and TEP techniques jointly compared with the Lichtenstein operation<sup>240</sup>. This subgroup analysis found significant advantages for the laparo-endoscopic procedures when compared with the Lichtenstein repair including: a lower incidence of wound infection (OR 0.39; 95 % CI 0.26 – 0.61; p=0.00003), a reduction in hematoma formation (OR 0.69; 95 % CI 0.54 – 0.90; p=0.005), and nerve injury (OR 0.46; 95 % CI 0.35 – 0.61; p<0.00001), an earlier return to normal activities or work (-1.35; 95 % CI -1.72 - -0.97; p<0.00001), and fewer incidences of chronic pain syndrome (OR 0.56; 95 % CI: 0.44 – 0.70; p<0.00001)<sup>240</sup>. No difference was found in total morbidity or in the incidence of intestinal lesions, urinary bladder lesions, major vascular lesions, urinary retention and testicular problems<sup>240</sup>. Significant advantages for the Lichtenstein repair included a shorter operating time (TAPP/TEP 65.7 min (40 - 109) vs Lichtenstein 55.5 min (34 - 99); p=0.01, a lower incidence of seroma formation (OR 1.42; 95 % CI: 1.13 - 1.79; p=0.003), and fewer hernia recurrences (OR 2.00; 95 % CI: 1.46 - 2.74; p=0.00001)<sup>240</sup>. The latter was strongly influenced by the Veterans Affairs Multicenter Trial, where the minimum mesh size in endoscopic surgery was 7.6x15cm<sup>241</sup>. When this study is excluded, there is no difference in the recurrence rates between open and laparo-endoscopic surgery.

### RCTs

For comparison of the laparo-endoscopic (TEP, TAPP) with the open Lichtenstein technique for male primary unilateral inguinal hernia many studies must be excluded. This is because they included female patients, bilateral hernias and/or recurrent hernias or compared TEP and TAPP with other open procedures or used to small meshes or combined IH repair with laparoscopic cholecystectomy<sup>202,205,210,220,223,242–273</sup>. In the comparison of 1,237 laparo-endoscopic (TEP, TAPP) operations with 1,281 Lichtenstein operations from RCTs fulfilling the inclusion criteria<sup>212,213,274–284</sup>, no differences have been observed in the intraoperative or postoperative complications following primary unilateral IH repair in males. Clear advantages have been observed for the laparo-endoscopic techniques in terms of early postoperative pain, analgesic consumption, and return to normal daily activities and to work. When the surgeon had sufficient experience in the respective technique, (i.e. after completing the learning curve), no significant difference was detected in the recurrence rate (TEP vs Lichtenstein with median follow-up of 5.1 years 2.4 % vs 1.2 %; p=0.109 and TAPP vs Lichtenstein with median follow-up of 52 months 1.3 % vs 1.2 %; ns)<sup>278,284</sup> between the laparo-endoscopic and Lichtenstein techniques. Likewise,

chronic pain occurred significantly less often after laparo-endoscopic than after Lichtenstein operation (TEP vs Lichtenstein with follow-up of 5 years 9.4 % vs 18.8 % and TAPP vs Lichtenstein with median follow-up of 52 months 0 % vs 3.9 %) <sup>280,283</sup>. In the three RCTs <sup>276,277,281</sup> with at least 100 patients in each arm, the operative time for TEP was either similar to, or shorter than, the Lichtenstein operative time. The direct operative costs for laparo-endoscopic techniques are higher than for the Lichtenstein operation <sup>212,274,275,280</sup>. However, that difference decreases when all community costs are taken into account <sup>274,280</sup>.

### *Large database studies*

A 2015 analysis of the Herniated Registry compared the prospective data collected for males undergoing primary unilateral IH repair using either TEP or open Lichtenstein repair <sup>285</sup>. Inclusion criteria were: a minimum age of 16 years, male gender, primary unilateral IH, elective operation and availability of data on 1-year follow-up by a questionnaire of the general practitioner and patient. In total, 17,388 patients were enrolled, 10,555 (60.70 %) had a Lichtenstein repair and 6,833 (39.3 %) a TEP repair.

On multivariable analyses, surgical technique had no significant effect on the recurrence rate (estimated OR 0.775 95% CI 0.549-1.093; p=0.146) or on the chronic pain rate needing treatment (estimated OR 1.066 95% CI 0.860-1.321; p=0.560). Nor did the complication-related reoperation rates differ significantly between the two techniques (estimated OR 1.356 95% CI 0.960-1.913; p=0.084). TEP was found to have benefits on the postoperative complications rate (estimated OR 2.152 95% CI 1.734-2.672; p<0.001), pain-at-rest rate (estimated OR 1.231 95% CI 1.049-1.444; p=0.011), and pain-on-exertion rate (OR 1.420 95% CI 1.264-1.596; p<0.001).

### *Guidelines*

The 2009 EHS guidelines concluded <sup>3</sup>, mainly on the basis of a 2005 meta-analysis <sup>240</sup>, that endoscopic IH techniques result in a lower incidence of wound infection, hematoma formation and an earlier return-to-normal activities or work than the Lichtenstein technique. Laparo-endoscopic IH techniques have a longer operative time and a higher incidence of seroma formation than the Lichtenstein technique. Endoscopic repair results in a lower incidence of chronic pain/numbness than the Lichtenstein technique.

The learning curve for performing a laparo-endoscopic hernia repair, especially TEP, is longer than that for open Lichtenstein repair, and ranges between 50 and 100 procedures, with the first 30 to 50 being most critical <sup>3</sup>.

From a hospital perspective, an open mesh procedure is the most cost-effective operation <sup>3</sup>. In cost-utility analyses including quality of life, endoscopic techniques may be preferable since they cause less numbness and chronic pain <sup>3</sup>.

In the 2014 EHS guidelines update <sup>4</sup> a new meta-analysis was included. It contained studies with a follow-up of more than 48 months (including two new RCTs on TEP vs Lichtenstein). There was a non-significant difference in severe chronic pain (p=0.12) and in recurrence when data from one surgeon in the Eklund trial <sup>278</sup> were excluded. This was because of unacceptable recurrence rates in the endoscopic group (32%) due to technical failure.

## **Discussion, Consensus and Grading Clarification**

When the surgeon has sufficient experience in the respective techniques, laparo-endoscopic and Lichtenstein techniques have comparable operation times, perioperative complication rates needing reoperation and recurrence rates. Endoscopic techniques show advantages in terms of early and later postoperative pain and speed of recovery. In the EHS guidelines update, data was analysed from studies with a follow-up of more than 48 months. This analysis yielded a non-significant difference in severe chronic pain and long-term recurrence. The direct operative costs for laparo-endoscopic IH repair are higher, but fall to levels comparable with the Lichtenstein repair when considering quality-of-life aspects and total community costs. Study quality heterogeneity—lack of clear pain endpoints, definitions, quality of surgeon’s technique, caseload per surgeon, and lack of hernia classification—make the evaluation of complication risks difficult. Furthermore, there is a well-documented difference in learning curve and initial costs favoring Lichtenstein.

Large RCTs with good external validity and large-scale database studies are urgently needed to compare endoscopic with Lichtenstein operations for primary unilateral IHS in males. These studies must carefully select participating surgeons, to ensure that the learning curve has been completed for the respective surgical technique. A major investment is needed worldwide to make the learning curve for (laparo-endoscopic) hernia surgery as smooth as possible by ensuring optimal training facilities and circumstances.

HerniaSurge recommends a standardization of the laparo-endoscopic techniques, structured training programs and continuous supervision of trainees and surgeons within the learning curve.

**KQ06.g** In males with unilateral primary inguinal hernias which is the preferred repair technique, laparo-endoscopic (TEP/TAPP) or open pre-peritoneal?

F. Berrevoet, M. Misra and D. Chen

## Introduction

Evidence suggests that pre-peritoneal mesh placement is preferred over anterior mesh placement because of the physiologic mesh location and placement of the mesh away from the groin nerves. There is clinical interest about whether the various surgical approaches to achieve pre-peritoneal mesh positioning leads to different patient outcomes. Laparo-endoscopic IH repair has been studied in detail with good results, but has a rather long learning curve, potentially higher procedure costs and risks associated with general anesthesia. Additionally, logistical and financial constraints may limit the availability of quality laparo-endoscopic repairs, especially in lower resource settings.

## Statements and Recommendations

<i>Statement</i>	The outcome measures of morbidity, mortality, and recurrence rates do not seem not significantly different between laparoscopic and open pre-peritoneal repair.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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<i>Statement</i>	With regards to visualization, laparoscopic pre-peritoneal repair is a safe and standardized operation with possible technical advantages over open.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Especially in lower resource settings, techniques utilizing open pre-peritoneal mesh placement may become an acceptable alternative to laparoscopic pre-peritoneal mesh repair.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	No recommendation to advocate laparoscopic pre-peritoneal mesh placement over open pre-peritoneal repairs can be made due to insufficient and heterogeneous data.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

## Evidence in Literature

The literature comparing laparo-endoscopic techniques with open pre-peritoneal mesh placement for primary unilateral IHs is extremely limited and heterogeneous.

A 2002 meta-analysis compared laparo-endoscopic IH repair with open IH repair techniques<sup>286</sup>. However, the early laparo-endoscopic trials control groups included in this meta-analysis were poorly standardized; and often included only suture repairs such as the Bassini, McVay, or Shouldice. In later studies, plug-and-patch repairs were the main cohort in the groups that considered open pre-peritoneal mesh techniques.

Although the authors concluded that open pre-peritoneal hernia repair provides equivalent outcomes at lower costs and has potentially less severe complications compared with laparoscopic techniques, the included studies and available literature do not address our key question adequately.

An RCT of 49 patients compared open pre-peritoneal repair and TAPP<sup>287</sup>. This small study concluded that the open repairs were associated with fewer complications and recurrences and that laparoscopic TAPP was associated with higher costs but no advantage in median time to return-to-work.

In contrast, the SCUR Hernia repair study<sup>288</sup>, which compared 613 patients randomized to three groups (open suture repair, open pre-peritoneal repair by split incision with polypropylene mesh and TAPP) demonstrated that although TAPP resulted in both shorter time to full recovery and shorter time to return-to-work, it was more expensive and had a higher complication rate. There was no significant difference regarding recurrences at one year in the three groups (3% overall). Another small four-arm randomized trial of 100 patients studied laparoscopic TAPP and TEP as well as open pre-peritoneal repair and Lichtenstein repair<sup>213</sup>. The laparoscopic repair groups showed less postoperative pain and achieved significantly faster return-to-normal domestic activities and to-work compared to Lichtenstein repair patients. However, this study is of low methodological value according to SIGN criteria.



The currently available literature does not allow us to provide any recommendation about whether laparoscopic mesh placement in the pre-peritoneal plane is superior to open pre-peritoneal techniques.

**KQ06.h** Which is the preferred technique in Bilateral hernia.

The EHS guidelines concluded with only moderate evidence that bilateral hernia is preferably treated by a laparo-endoscopic method provided expertise is available<sup>3</sup>. This seems self-evident as the advantages of laparo-endoscopic repair (faster recovery, lower risk of chronic pain and cost effectiveness) are increased when performing two hernia repairs via the same three key hole incisions. No new high level research was found so the recommendation of the EHS guidelines have been copied in the HerniaSurge guidelines. The EAES guidelines concluded that especially in bilateral groin hernia an endoscopic approach to be an excellent choice (level 1B consensus 96%)<sup>6</sup>. (see also chapter 7 individualisation).

### Recommendation

<i>Recommendation</i>	From a socio-economic perspective, a laparo-endoscopic repair is recommended in bilateral hernia repair, provided expertise is available	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *upgraded
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## Chapter 7 Individualization of Treatment Options

B.J. van den Heuvel, M.P. Simons and U. Klinge

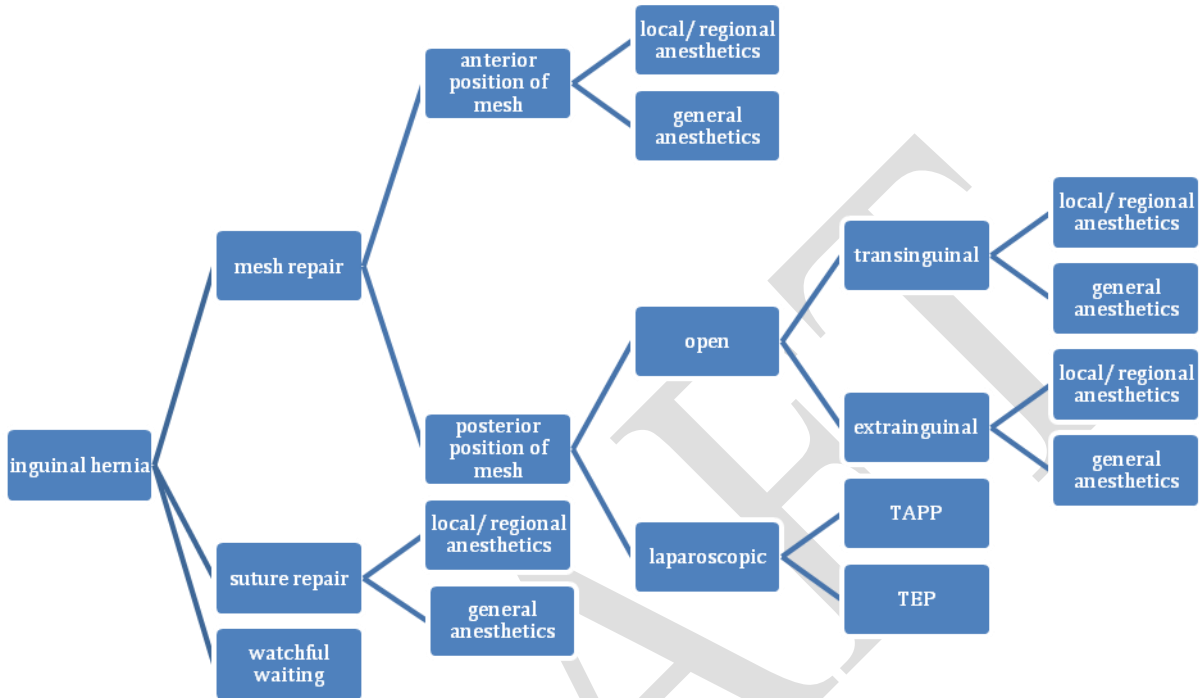
### Introduction

Inguinal hernia treatment has changed markedly over the past seven decades. Prior to the 1950s, hernia surgery involved an anatomical reconstruction of the inguinal canal with sutures<sup>3,5,213,221,232,252,254,278,279,284,289–310</sup>. When the tension-free mesh repair was introduced it resulted in a hernia repair revolution. Many new mesh applications and variations were developed including: open, anterior and posterior approaches, and endoscopic techniques (Figure 1)<sup>3,5,213,221,232,252,254,278,279,284,289–310</sup>.

All mesh repairs have essentially comparable outcomes. Therefore, the question confronting hernia surgeons is, “which technique should be used in which case?” Individual techniques have varying advantages and disadvantages such as: the possibility of surgery under local anesthetic, simultaneous contralateral side repair, avoiding scar tissue in recurrent hernias by choosing a different approach, amongst many others. As a result, questions arise. Which factors should

properly guide surgical decision making? Can IH treatment be standardized, or should it be individualized? If individualized, which determinants should influence surgeon's choices?

We have tried to answer the questions posed.



**FIGURE 1. TREATMENT OPTIONS FOR INGUINAL HERNIA**

### Key question

**KQ07.a** In inguinal hernia repair, when should treatment be individualized?

### Recommendations

<b>Recommendation</b>	In patients with primary bilateral hernias a laparo-endoscopic approach is recommended provided expertise is available.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Strong</b> <b>*Upgraded</b>
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<b>Recommendation</b>	In patients with pelvic pathology or scarring due to radiation or pelvic surgery, or for those on peritoneal dialysis, consider an anterior approach.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Strong</b> <b>*Upgraded</b>
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<b>Recommendation</b>	It is recommended that surgeons tailor treatments based on expertise, local/national resources, and patient- and hernia-related factors.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Strong</b> <b>*Upgraded</b>
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<b>Recommendation</b>	Since a generally accepted technique, suitable for all inguinal hernias, does not exist, it is recommended that surgeons/surgical services provide both an anterior and a posterior approach option.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<b>Strong</b> <b>*Upgraded</b>
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## Evidence in Literature

There are no reviews, RCTs or cohort studies comparing different techniques in specific situations. Since no mesh technique is proven to be superior, technique chosen often depends on surgeons' preferences.

One 2012 publication addresses surgical preferences in IH repair<sup>311</sup>. A survey questionnaire was distributed to 100 endoscopic surgeons at the 2010 European Association of Endoscopic Surgery annual meeting. The participating surgeons were asked to indicate preferred surgical technique in specific clinical scenarios, including patient age, gender, physical activity capabilities, physical characteristics, emergency situations, and hernia size and type. Surgeons were able to choose between open, TAPP or TEP repair in a variety of patient scenarios. Eighty-two percent of the surgeons chose a tailored approach and indicated that their choice of repair depended on the listed patient characteristics. Interestingly, only 6% of the surgeons were able to routinely offer patients all three techniques.

## Discussion, Consensus and Grading Clarification

The HerniaSurge Group has identified possible factors influencing the type of IH repair. These factors involve: patient characteristics, surgical expertise, local/national resources, and logistics (Table 1). Future research must address the issue of individualized treatment in specific cases. The HerniaSurge Group currently offers consensus-based examples of tailored surgical approaches in specific circumstances.

**TABLE 1. DETERMINANTS OF SURGEONS' PREFERENCES**

<b>PATIENT CHARACTERISTICS</b>	High preoperative pain
	Gender
	Comorbidity (smoking, collagen disease, obesity, ascites)
	Previous medical history (pelvic surgery, pelvic radiation, lower abdominal surgery)

	Previous hernia surgery Occupation Physical activity Age Contraindication for general anesthetics
<b>HERNIA CHARACTERISTICS</b>	Size  Type Primary or recurrent Reducibility Unilateral or bilateral
<b>EMERGENCY SITUATION</b>	Incarcerated hernia  Strangulated hernia

### Additional Recommendations for Individualisation

In the different chapters of these guidelines some recommendations are made with regards to indicated surgical technique. We have outlined these recommendations in this chapter, but refer to these specific chapters for detailed background information. In addition to these recommendations the consensus-based recommendations are outlined.

For recurrent IHs, use the opposite approach (e.g. for recurrence after anterior repair use a posterior technique, and vice versa). (chapter 10)

In high-risk IH patients with extensive comorbidities consider an open mesh repair under local anesthesia. (chapter 16)

For IH patients with high preoperative pain, consider laparo-endoscopic repair. (chapter 18)

Consider a laparo-endoscopic approach in active young patients with IHs. (chapter 18)

In femoral hernia patients a pre-peritoneal mesh repair is recommended. (chapter 25)

In female patients with IHs a laparo-endoscopic repair is recommended. (chapter 26)

Use a laparo-endoscopic approach in patients with bilateral IHs.

In patients with pelvic pathology or scarring due to radiation or pelvic surgery, or for those on peritoneal dialysis, consider an anterior approach.

## Chapter 8 Occult Hernias and Bilateral Repair

A.C. de Beaux, N. Schouten and J.F. Kukleta

### Introduction

An occult hernia, as defined by the HerniaSurge Working Group, is an asymptomatic hernia not detectable by physical examination.

IH formation is considered a bilateral condition based on etiology, yet for many patients presentations with a unilateral symptomatic hernia is typical. Occasionally, a contralateral hernia will be evident on physical examination, but a number of patients will have a contralateral occult hernia at time of initial presentation which may become symptomatic later. Another patient subset will develop a contralateral hernia *de novo* which may require repair.

### Key Questions

**KQ08.a** In those with unilateral overt primary IHs, what is the likelihood they will also have a contralateral occult IH?

**KQ08.b** In those with unilateral overt primary IHs, what is the likelihood they will develop contralateral overt hernias over time?

**KQ08.c** In patients who have undergone a unilateral TEP and negative contralateral exploration, what is the risk of developing an overt hernia on the disease-free side?

**KQ08.d** In cases where an occult contralateral IH is seen during TAPP will it become symptomatic if not repaired?

**KQ08.e** In those with overt unilateral primary IHs without contraindications to bilateral TEP or TAPP repair, should bilateral repair be performed?

### Statements and Recommendations

Statement	In patients with unilateral overt primary inguinal hernias, an occult contralateral inguinal hernia is seen at time of laparoscopic inguinal hernia surgery in up to 58% of cases.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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Statement	In patients who have undergone a unilateral inguinal hernia repair, the chance of developing a contralateral inguinal hernia increases with time; however, the true incidence is unknown.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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<i>Statement</i>	There is a low risk for the development of a contralateral overt inguinal hernia following a previously negative TEP exploration.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<i>Statement</i>	The percentage of occult hernias noted at TAPP that become symptomatic will increase over time; however, the true incidence is unknown.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<i>Recommendation</i>	It is recommended that the contralateral groin be inspected at time of TAPP repair. If a contralateral inguinal hernia is found and prior informed consent was obtained, repair is recommended.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *Upgraded
<i>Recommendation</i>	In those with overt unilateral primary inguinal hernias without contralateral hernias, routine bilateral TAPP repair is not suggested.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Weak
<i>Recommendation</i>	Routine exploration by TEP of the contralateral groin in an asymptomatic patient with no clinical hernia is not suggested.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Weak

## Evidence in Literature

Evidence for the recommendations and statements in this chapter is largely derived from retrospective case series involving relatively small numbers of patients. Some RCTs address certain aspects of the topics presented.

A number of studies have reported on the incidence of occult contralateral hernias at the time of bilateral TEP exploration for a clinically diagnosed unilateral hernia. These studies report incidence rates ranging from 5% to 58%<sup>312–320</sup>. In TAPP exploration, clinically occult contralateral hernias are observed in 13% to 22% of patients<sup>314,321,322</sup>. However, the laparoscopic parameters for contralateral hernia presence or absence are not well defined in these studies. Additionally, the natural history of these small incidentally-discovered defects is poorly understood and the clinical relevance of repair is unknown<sup>312</sup>.

In those with primary unilateral IHs, the lifetime risk of developing a contralateral IH is not known exactly. One study reported a 48% incidence of overt contralateral hernia development following TEP repair at 13 years follow-up<sup>58</sup>. Others report the incidence of subsequent contralateral hernia repair after primary unilateral TEP repair as: 3.2% at 3 years, 2.5% at 5 years, and 3.8% at 10 years<sup>323–325</sup>.

Several RCTs involving patients who have undergone repair of unilateral primary IHs have reported on contralateral hernia formation during various follow-up periods. One study reported a five-year 10% contralateral hernia incidence<sup>140</sup>. An RCT with a nearly 11-year follow-up compared open-suture to open-mesh repair of unilateral primary IHs and found contralateral hernia formation in 21% of non-mesh patients and 25% of mesh patients<sup>77</sup>. Another RCT of TEP

vs open-mesh repair, reported that 10.7% of the TEP repair group and 7.3% of the open-repair group developed contralateral hernias at five years<sup>326</sup>.

Some surgeons perform contralateral exploration at the time of unilateral primary IH TEP repair. Two retrospective cohort studies address this subject. Notably, the laparoscopic features of a normal groin versus an occult hernia are not defined nor are the nature and completeness of follow-up. One study, with a 5.9-year median follow-up, reported that 8.1% of patients developed a contralateral IH after unilateral TEP repair with negative contralateral exploration<sup>317</sup>. The annual calculated risk was 1.2% for contralateral hernia formation after a previously-negative TEP exploration (1.6% at one year, 5.9% at five years and 11.8% at 10 years). The median time to contralateral hernia development was 3.7 years (range 0-12 years). However, almost 60% of the study population had already undergone bilateral repair. The remaining 40% (409 patients) underwent unilateral repair and contralateral exploration and are therefore not representative of most hernia surgeon's practices. A second cohort study with 38-month median follow-up (range 10-82 months) reported a 1.1% incidence of contralateral overt hernia formation following unilateral TEP repair with contralateral exploration<sup>315</sup>. Thirty percent of the study population had already undergone bilateral repair.

Two studies address the subject of contralateral exploration at the time of unilateral primary IH TAPP repair. In one, the presence of a so-called incipient hernia was identified during TAPP contralateral exploration in 5% of patients<sup>321</sup>. An incipient occult hernia was defined as a looming or beginning hernia with a defect too small to allow protrusion. After a mean follow-up of 112 months (range 16-218 months) 21% of patients (13 patients) developed a symptomatic hernia. In the same study, a true contralateral occult hernia had been identified and repaired in 8% of patients during their initial surgery. Another study reported that with a 12-month median follow-up, six of 21 patients (29%) with a contralateral "incidental hernia defect" seen on TAPP exploration developed an overt (i.e. symptomatic) IH<sup>327</sup>.

Routine contralateral exploration or "preventative" mesh placement in a normal groin is controversial. Visualisation of the contralateral side in TAPP repair for an overt unilateral hernia is easily done without additional dissection of the contralateral side. However, without dissection of the contralateral side, some cases of lipoma of the cord will be missed. Unlike the TAPP approach, the TEP repair requires additional dissection to diagnose a contralateral hernia. Bilateral repair proponents cite a number of advantages to their approach including: poor clinical accuracy in hernia diagnosis especially in obese patients, the benefits to the patient and the healthcare system of one operation, and possible prevention of a hernia-related complications during future contralateral side surgery. Opponents focus on the potential to do harm to a normal or near-normal groin and the associated risk of chronic pain following surgery on a normal groin. There is a lack of evidence to allow good decision making on this issue. The decision to proceed with routine bilateral repair mandates appropriate informed consent and a high level of surgical skill.

A number of surgeons now perform "preventive" bilateral laparoscopic hernia repair in the majority of patients with symptomatic unilateral hernias<sup>316,328</sup>. Others advocate routine contralateral exploration with mesh repair in those in whom a "hernia defect" is found<sup>314,321,322</sup>. The decision to explore a potentially normal groin may be influenced by the surgeon's mind set, his operative expertise and his complication rate however the medical evidence to support this decision is either lacking or weak at present.

Most studies comparing the outcomes of unilateral versus bilateral TAPP repair, report a longer operation time, (in the region of 25 minutes) but no differences in morbidity, time to recovery, reoperation and recurrence rate<sup>322,329</sup>. One national cohort study reported a significant difference in the rate of postoperative surgical complications occurring within 30 days (such as hematoma, seroma and wound infection) between unilateral and bilateral IH repair by TAPP. The postoperative complications necessitated reoperation in 0.9 % of patients after unilateral, and in 1.9% of patients after bilateral, IH repair. However, this study reported that these differences in intraoperative and postoperative complications between unilateral and bilateral repair decreased in experienced high-volume hernia centers<sup>330</sup>. However, there is no evidence that exploration of a contralateral groin and mesh placement at TAPP when no hernia is present has the same risk as that of a true hernia repair.

In TEP repair, operation time is reported to be 7-10 minutes longer for a bilateral, compared to a unilateral, repair. No difference in recurrence rate, postoperative complications, conversion rate and time to recovery were reported by several studies<sup>313,316,317,319,331-333</sup>. One study did report a slightly increased risk of intra-abdominal complications (specific complications were not described) and surgical postoperative complications (hematoma, wound infection) in the bilateral TEP group compared to the unilateral TEP group<sup>334</sup>. Again, it is unknown if exploration of a normal groin carries the same risk as exploration of a groin with a hernia, although two studies have reported no significant morbidity from such a practice<sup>315,317</sup>.

Almost all the studies cited in this chapter suffer from data heterogeneity and lack of a uniform definition of “occult hernia.” Therefore, the category “occult hernia” might include those with: actual protrusion of normally intra-abdominal contents, a “beginning” hernia, or even just a patent *processus vaginalis* without herniation. A patent *processus vaginalis* is observed in 12% of patients but only 12% of these develop an indirect hernia within five years. This compares with 3% of patients with an obliterated *processus vaginalis*<sup>21,335</sup>.

Many of the important clinical questions on the subject of a proper approach to occult hernias cannot be definitively answered by the currently available evidence. It is, however, likely that up to 50% of patients who develop an IH, will either present with clinically evident bilateral IHs, or develop a contralateral IH in their lifetime. Risk factors to identify this group of patients and to inform the decision on bilateral repair should be areas of future research.

## Chapter 9 Day Surgery

W.M.J. Reinpold, H. Niebuhr and D. Lomanto

### Introduction

Day surgery for IH repair has become increasingly common over the past several decades. Synonyms for “day surgery” include: outpatient surgery, ambulatory surgery, same-day surgery, day case, and short-stay surgery and indicate that patient discharge occurs the day of operation. It is commonly known that day surgery is safe and feasible for many IH repairs. Several studies prove that day surgery is cost effective when compared with inpatient treatment. However, it is unclear which complex IHs should not be repaired as day cases. In these Guidelines, “complex



cases” include:

1. Groin hernias with signs of incarceration, strangulation, infection, relevant preoperative chronic pain, difficult local findings in the groin such as large (irreducible) scrotal hernias, (multiple) recurrence(s), recurrence with previous mesh repair, a relevant history of lower abdominal surgery, radiation, and comparable problems
2. Groin hernias in patients with relevant comorbidities, (cardiovascular / pulmonary / endocrine / immune deficiency / hepatic / renal / gastro intestinal / mental disorders / anxiety, immune deficiencies, post-transplantation status, coagulopathies, antithrombotic medications)
3. Difficult intraoperative findings (severe adhesions, abnormal anatomy, excessive bleeding) and intraoperative complications such as damage to viscera, blood vessels, nerves and genitals
4. Symptoms and signs of postoperative local complications (bleeding, hematoma, thromboembolism, urinary retention, bowel obstruction, peritonitis, sepsis, infection, orchitis) and/or general complications (cardiovascular, respiratory, renal, hepatic, gastrointestinal, cerebral organ failure, anxiety, psychic, mental distress)

The current evidence on ambulatory surgery for IH repair is presented.

### Key Questions

**KQ09.a** Which inguinal hernias can be safely repaired in day surgery?

**KQ09.b** Can endoscopic and open herniorrhaphies be performed safely in day surgery?

**KQ09.c** Can patients with severe comorbidities (ASA III or higher) be safely treated in day surgery?

**KQ09.d** Can patients with complex inguinal hernias (e.g. scrotal hernias) be safely treated in day surgery?

### Recommendations

<b>Recommendation</b>	Day surgery is recommended for the majority of groin hernia patients provided adequate aftercare is organized.	☒☒☒☐	<b>Strong</b>
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<b>Recommendation</b>	Day surgery is suggested for all endoscopic repairs of simple inguinal hernias provided adequate aftercare is organized.	☒☒☐☐	<b>Weak</b>
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<b>Recommendation</b>	Day surgery is suggested for selected older and ASA IIIa	☒☒☐☐	<b>Weak</b>
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patients (open repair under local anesthesia) provided adequate aftercare is organized.

<i>Recommendation</i>	Day surgery for patients with complex inguinal hernias is suggested only in selected cases.	☒☐☐☐	Weak
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## Evidence in Literature

Day surgery for IH repair involves patient discharge the same day of surgery after a period of medically supervised recovery<sup>336</sup>.

Nineteen fifty-five marks the first publication on the advantages of day surgery repair of IH including: quicker mobilization, lower cost and a patient-friendly experience<sup>337</sup>. Subsequently, several retrospective case series and three small randomized studies were published comparing inguinal herniorrhaphy day surgery with inpatient treatment<sup>338–341</sup>. Another randomized study surveyed patient preference for site (inpatient or outpatient) of surgery<sup>342</sup>. These studies all concluded that day surgery is cheaper than, and as safe and effective as, inpatient repair of selected IHs. Additionally, many cohort studies exist concerning various other aspects of day surgery for IHs. These studies span the outpatient surgery spectrum including: general, regional and local anesthesia; classical operative techniques; open tension-free repairs; and endoscopic techniques. All support the notion that day surgery is a safe option for many IH patients.

A 2006 Danish study of nearly 19,000 day surgery patients noted a 0.8% hospital readmission rate<sup>343</sup>. A 2012 Danish multicenter study of over 57,700 day surgeries found a 1.1% complication rate leading to hospital readmission following day surgery for IHs<sup>344</sup>. According to a publication of outpatient surgery including groin hernia repair in more than 564,000 United States Medicare beneficiaries older than 65 years, the 7-day mortality rate was 37 per 100,000 cases. However, there are no reports in the medical literature of death or severe complications being directly related to day surgery.

Although tension-free repair under local anesthetic seems most suitable for day surgery, published series support the use of other surgical and anesthetic techniques in this setting. Day surgery should be considered for all simple inguinal herniorrhaphies (both open and endoscopic) provided adequate aftercare is organized<sup>276,344,345</sup>. However, after laparoscopic repair (TAPP/TEP) and posterior open-mesh repair, severe pre-peritoneal or retroperitoneal bleeding, may occur in rare circumstances. In most cases, this infrequent complication occurs within the first 48 hours postoperatively. Since the laparoscopic management of large hematomas is often only possible after immediate diagnosis, short stay treatment of these patients can also be considered. There are no reports of Stoppa's open pre-peritoneal approach being performed on outpatients.

There are insufficient data to routinely recommend outpatient repair of complex IHs (see above). However, if adequate aftercare is arranged, some of these cases may be suitable for ambulatory surgery.

Operations on strangulated and acutely incarcerated hernias should not be performed as day

cases.

Barring the exclusions cited above, IH day surgery can be considered for every patient with satisfactory care at home, including stable ASA III patients<sup>346–350</sup>.

Day surgery should also be considered for the elderly, including octogenarians<sup>351–353</sup>. However, nonagenarians should be excluded since even elective IH repair in those over 90 has a tenfold higher mortality rate compared with younger patients<sup>354</sup>.

A recent publication based on data from 82,911 patients with IH operations documented in the German hernia registry “Herniamed” revealed that patients with prophylactic or therapeutic use of platelet aggregation inhibitors and oral anticoagulants had a significant higher risk of bleeding complications (3.9 % vs 1.1 %;  $p < 0.001$ ) compared to those patients without such a medication<sup>355</sup>. These data suggest that IH day surgery of patients on anticoagulants cannot generally be recommended.

A number of additional factors will either encourage or discourage day surgery. The anesthesiologist’s preoperative assessment is extremely important, because he has primary responsibility for the perioperative- and immediately-postoperative phase<sup>348</sup>. Other hospital-, physician- and patient-related factors must be considered also<sup>336</sup>. In a facility with considerable day surgery experience and a good infrastructure (i.e. easy availability of pre-assessment consultation and a smoothly functioning day surgery center), a large percentage of IH repairs may occur in day surgery. Surgical factors (quick operations and few complications) and anesthetic factors (effective pain and nausea control making rapid patient discharge possible) may influence the decision to proceed with day surgery.

Day surgery for IH repair is becoming increasingly more popular<sup>345,347</sup>. In Spain in 2005, day surgery inguinal herniorrhaphies constituted 34% of the total<sup>356</sup>. From 2000 to 2010 the rate of IH day surgeries in the Netherlands increased from 36% to 54%<sup>261,354</sup>. Data from the Swedish National Registry indicate that 75% of IH repairs are performed in day surgery. From 2000 to 2009 the incidence of day surgery for IHs increased from 62% to 87% in the Northern Italian Veneto region<sup>349</sup>. However, this considerable regional variation is not explained solely by the scientific evidence supporting the acceptability of day surgery IH repair. It is posited that healthcare financing and reimbursement also play a role<sup>357</sup>.

## Discussion

Our present and future challenge is to provide ever more effective, less invasive, and safe ambulatory hernia surgery to a broadening array of complex, aged and sicker patients. More studies are needed on these high-risk groups to determine acceptable safety and outcome parameters. For now, the available evidence supports the idea that many patients are well served by day surgery repair of IHs.

## Chapter 10 Meshes

D. Weyhe and U. Klinge

## General Introduction

Modern mesh implants must possess certain mechanical and biological properties including for instance: elasticity while maintaining the capacity to withstand stresses, resistance to repetitive mechanical load, and good biocompatibility, permitting quicker return to work and reducing chronic groin pain. Therefore, mesh biocompatibility has been the focus of many studies, and the definition of biocompatibility has shifted, from a biochemically inert conceptualization to an application-oriented one. Another shift has been in mesh improvements, many focused on the prevention or minimization of adverse effects such as chronic groin pain or movement-dependent discomfort, thereby permitting quicker return to work and normal daily activities. As a result, light meshes have been developed and employed in recent years<sup>5</sup>.

The “ideal mesh” is difficult, if not impossible, to describe and regardless does not exist for all applications. In addition, complications in mesh-based hernia surgery are not always purely mesh-related and may result from failures during the surgical procedure, impaired wound healing, and/or by material-induced inflammation and scarring with subsequent functional damage. Most studies of mesh complications do not stratify for radical differences in patient groups. In ideal patients undergoing perfect surgery in expert centers (group 1) the impact of particular mesh type on the development of complications can be studied in near-isolation. In patients with major surgical trauma (group 2) or in those with poor wound healing capability (group 3) the impact of material type alone on complications is far more difficult to discern. Even in large studies, patients with purely material-related complications constitute a minor subpopulation of the study cohort. Additionally, a mix of risk factors for complications is always at play. These limitations and confounders mean that statistically significant differences are hardly ever achieved in studies comparing materials. Furthermore, it is difficult to pinpoint a material’s particular characteristic that leads to complications. Weight, elasticity, strength and porosity all influence tissue reaction. Therefore, it is challenging, if not frankly impossible, to define critical margins that separate low-risk from high-risk constructions.

Given the huge variety of meshes and their plethora of modifications and combinations, it is impossible to clearly define general risk conditions for a specific mesh type in a given anatomical location. Any risk assessment must consider different complications, for which the mesh’s contribution to the risk is estimated.

As of the writing of this chapter, high-quality RCTs and meta-analyses comparing materials are not available to strongly guide decision-making in the clinical setting. This fact, coupled with the limitations cited above, means that mostly preclinical trials and tests (always GRADE “low”) are used for our recommendations and statements below. Perhaps in the future, registry data may provide information on whether predictive classifications for complications are confirmed in clinical settings. Additionally, registry data may be able to help determine which mesh construction offers the best risk/benefit ratio in specific hernia subgroups.

## Mesh characteristics

### Introduction

The rationale behind many mesh modifications is the assumption that material selection favorably impacts surgery outcomes and patient wellbeing. Since many meshes exist with widely overlapping properties, our focus below is on the general influence of meshes.

Also, because textile 3D constructions or plugs induce completely different foreign-body reactions and scar plates, **KQ10.a** is focused on flat and large-pore-size meshes since in patient groups received these products, outcomes seem more comparable. A pore size > 1.0 mm generally defines “large-pore-size” but there is no consensus on this definition. Some guidelines use a definition for large-pore-size as > 1.5 mm<sup>226</sup>. For the newer meshes, larger pore size is usually associated with reduced weight.

### Key Question

**KQ10.a** Do mesh characteristics (i.e., flatness and pore size) have an impact on outcome?

### Statements and Recommendation

Statement	Evidence supports the contention that mesh characteristics influence clinical outcomes.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
Statement	The effect of pore size <u>alone</u> on clinical outcome has not been investigated in clinical trials; therefore, no recommendation can be made.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
Recommendation	Hernia surgeons should be aware of the clinical characteristics of the meshes they use.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *upgraded

### Evidence in Literature

#### Flat meshes

Overall, 23 RCTs relate mesh material to some clinical outcome<sup>149,165,171,183,358–376</sup>. Eight of the 23 RCTs did not find significant differences. However, all the trials are small and are underpowered to detect many differences of practical concern. Therefore, the lack of any significant difference does not automatically imply equality of the compared meshes with regards to the observed outcome, and thus provide no arguments against a possible impact of the mesh material for outcome.

There is strong evidence that mesh selection can change clinical outcomes (e.g. foreign-body sensation, chronic pain, sperm motility<sup>377</sup>, recurrence). The effect of mesh selection on risk/benefit ratios for individual patients has yet to be defined.

### *Large pore size meshes*

Currently, no distinction is made between large-pore-size and lightweight meshes. Research to date has focused only on mesh weight. Clinical trials comparing only meshes of different pore size (large versus small) do not exist. However, preclinical studies suggest that > 1.8 mm pore-size meshes positively influence integration into adjacent tissue<sup>378–380</sup>.

### *Lightweight meshes*

## **Introduction**

Lightweight meshes (LWM) are typically defined as mesh constructs with large pore size and reduced weight. However, lightweight meshes with small pores are also available. Considering the major impact of pore size on tissue reaction, comparisons of meshes with different weight have to include only materials with similar pore sizes. There are only a small number of studies on this issue, which compare different outcomes of only large pore meshes of different weight in Lichtenstein, TEP or TAPP surgery. These studies will be discussed in this section.

## **Key Question**

**KQ10.b** Do lightweight meshes have benefits in open or laparoscopic IH repair?

## **Statement and Recommendation**

<b>Statement</b>	Use of so-called LWM in inguinal hernia surgery (open and laparo-endoscopic) may have some short-term benefits (reduced postoperative pain and shorter convalescence).	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
<b>Recommendation</b>	Before a clear definition of LWM and HWM exists, the selection of mesh based solely on the terms “lightweight” or “heavyweight” is not recommended.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *upgraded

## **Evidence in Literature**

### *Open surgery*

All short-term follow-up studies of LWM in Lichtenstein repairs report a lower incidence of pain<sup>372,381–383</sup>. In longer-term follow-up (3-5 years) there is no difference in reported pain

between LWM and HWM repairs<sup>358,365,372,383</sup>, except in one RCT which reported a lower incidence of chronic pain with LWM<sup>366</sup>. The incidence of foreign body sensation tends to be less with LWM as well<sup>358,366,368,384</sup>. There is no reported difference in the incidence of recurrence over the long-term<sup>358,366,383</sup>. Notably, the absence of a significant difference is due to the small numbers of recurrences in the studies cited.

### *TAPP surgery*

When considering pain and postoperative recovery following TAPP, LWMs are superior to the so-called HWM, especially older generation HWM, whereas this difference was not found between the so-called moderate and the extra-light meshes<sup>385</sup>. One study did find a significant difference between light (35g/m<sup>2</sup>) and very-lightweight mesh (15g/m<sup>2</sup>) in TAPP repairs with a 3-year follow-up. A lower incidence of chronic pain with the use of extra-light mesh was also shown in this study<sup>386</sup>. Another study showed that, despite higher perioperative analgesia requirements with HWM, the incidence of chronic pain is similar to that seen with LWM<sup>387</sup>. Recurrence rates following TAPP repairs are the same with LWM and HWM<sup>385</sup>.

### *TEP surgery*

At this writing, 1,650 patients have been studied over periods ranging from three to 12 months in prospective randomized trials. Most studies have found advantages to LWM in TEP surgery<sup>3,226,358,361,362,364–366,368,372,376,382–412</sup>. **KQ10.c** will further address the issue of whether mesh weight alone is a single predictive factor for surgical outcomes.

## **Discussion**

In studies of HWM and LWM, LWMs were superior, or at least comparable to, HWM with regards to observed outcomes, regardless of surgical approach. However, a recommendation resting solely on mesh weight cannot be supported by evidence since varying pore sizes amongst the various LWM and HWM is not considered in any available study.

### *Mesh weight*

## **Introduction**

There is an ongoing debate about the mesh type best suited for IH repair. So-called LWMs are found to result in higher recurrence rates than so-called HWMs<sup>361</sup>. However, LWMs often produce less chronic pain and foreign body sensation<sup>413,414</sup>. The analysis presented below—with special attention to data from meta-analyses—is intended to clarify the issue. However, as previously noted, no studies are available which consider only weight as the single predictive factor for surgical outcomes.

## **Key question**

## KQ10.c Are clinical outcomes influenced by mesh weight (evidence from meta-analyses)?

### Statements and Recommendation

Statement	Recently published meta-analyses and RCTs do not support the contention that LWMs in groin hernia surgery are associated with better postoperative outcomes.	☒☒☒☒	
Statement	Subset analyses did not find higher recurrence rates with the use of LWMs in laparoscopic inguinal hernia repair.	☒☒☒☒	
Statement	There exists no clearly defined weight limit for LWMs and HWMs. Therefore, the effect of weight differences alone on surgical outcomes is unknown.	☒☒☒☒	
Recommendation	Mesh selection based on weight alone is not recommended nor supported by the available literature.	☒☒☒☒	Strong

### Evidence in Literature

Three meta-analyses reviewing various aspects of TEP or TAPP laparoscopic surgery have been recently published<sup>413–415</sup>. LWM and HWM differences were part of the reviews. Review results varied slightly with regard to endpoints, recurrence rates, postoperative pain, chronic pain, return-to-work and seroma formation. One of the meta-analyses concluded that short- and long-term results following surgery with either LWM or HWM are comparable across all relevant endpoints<sup>415</sup>. A second concluded that there are probably higher recurrence rates with LWM but less groin pain and foreign body sensation<sup>413</sup>. The third also concluded that LWM was associated with less groin pain and foreign body sensation but found no increase in recurrence rate<sup>414</sup>. All called for more study on the topic; two suggested that studies with longer follow-up times be performed.

The three meta-analyses differ broadly due to study selection for inclusion, heterogeneity of the selected studies, and quality assessment of the included studies.

Additionally, the three meta-analyses only included RCTs published prior to 2012. Since then, two relevant RCTs have appeared. A large 2015 study found no difference between LWM and HWM in the incidence of groin pain and foreign body sensation<sup>388</sup>. A 2012 study concluded that, compared with a HWM, a LWM provided no reduction in chronic groin pain and foreign body sensation at three-year follow-up<sup>358</sup>. There were no inter-group differences in recurrence rates.



## Discussion

Regarding the many debates over different techniques and different implants, the quality of the meta-analysis studies on mesh is crucial for good decision making and guidance of surgical practice. Unfortunately, most of the studies demonstrate a considerable heterogeneity when defining inclusion criteria, comparing techniques and material, or outcome, thus reaching conflicting conclusions.

For instance, increased LWM-related recurrence rates after 12 months in TEP and Lichtenstein are reported in two prospective studies<sup>361,416</sup>. According to one study's authors, the increased rate of recurrence is more due to the fixation technique than the mesh itself<sup>416</sup>, and the long-term observations (> 12 months) for hernia recurrences reveal no significant differences by use of so-called lightweight meshes.

Also, selection criteria remain quite unclear in some cases. For example, a 2012 publication did not take into account some prospective randomized trials<sup>373,385,387</sup>, and instead case control studies were included<sup>417</sup>. A 2013 article did include the aforementioned studies, but also included a surgeon's-choice randomized study that was mistakenly considered to be computer generated. Also, the three meta-analyses from 2012 and 2013 do not properly account for differences in fixation techniques. Some of the included studies do not describe the mesh fixation technique used or they compare different fixation methods<sup>364,374–376,387,418,419</sup>. Nor is an adequate discussion of the relevance of mesh fixation versus mesh weight included.

*Mesh foreign body reaction*

## Introduction

Mesh implantation induces a foreign body reaction in the recipient's tissues leading to an encapsulation of the polymer fibers by a granuloma of inflammatory and fibrotic cells. Since inflammation is related to scar formation, any chronic inflammatory process results in permanent cell turnover which in turn leads to scar accumulation and constantly increasing collagen deposition. Considering the functional consequences of excessive scarring, the matter of chronic inflammation at mesh/tissue interfaces is important since it may represent a permanent risk for patients. A related issue is whether the foreign body reaction attenuates over time. Both issues impact risk assessment for mesh implants.

## Key Question

**KQ10.d** Does chronic inflammation occur at mesh/tissue interfaces?

## Statements and Recommendations

none

## Evidence in Literature

Tissue reaction to mesh has been studied in various animal models (e.g. mice, rats, rabbits, sheep and others) with a follow-up of up to two years in rodents and up to three years in sheep. All these studies confirm persistent chronic inflammation at mesh/tissue interfaces as a consequence of physiologic foreign body reactions. Inflammation intensity varies with mesh location, animal species, mesh material, textile construction, time and individual host response.

Studies of human mesh explants were published in 2007 and 2012 with follow-ups of three to 15 years<sup>420,421</sup>. Most meshes were explanted due to complications, which may lead to increases in local inflammation, whereas some mesh/tissue specimens were taken as biopsies during revision procedures for other reasons. Although inflammatory intensity varied considerably, a foreign body granuloma with macrophages and foreign body giant cells (reflecting persistent inflammation) has always been confirmed. Since chronic inflammation potentially stimulates local fibrosis and scar formation, long-term complications of this mesh-adjacent process must be considered. The risk/benefit ratio for patients is unknown presently.

### Migration

## Introduction

Migration of foreign bodies in human tissue is a well-known phenomenon. Mesh is placed in soft tissues with rapid remodeling of adjacent tissues. When biomechanical strain occurs, mesh migration is often observed in the direction of the pulling forces.

## Key Question

**KQ10.e** Is late-onset mesh migration unavoidable?

## Statements and Recommendations

<i>Statement</i>	There is a lifetime risk for mesh migration which seems to be higher with plugs versus flat mesh.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Recommendation</i>	There is a lifetime risk for mesh migration. Mesh-related complications—including erosion and migration— should be considered in the differential diagnosis in patients with relevant symptoms in the region of their mesh.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> Strong

## Evidence in Literature

Mesh migration has been reported with all current polymers and following all hernia repair procedures<sup>422–488</sup>. A major message of all relevant studies is the fact that 20 postoperative years may pass before symptoms of mesh migration occur.

Risk of mesh movement is reduced by the use of large flat mesh in a tension-free setting. Smaller mesh surface area and tensile forces on the mesh increases the risk. Correspondingly, for groin hernias specifically, most reports describe early (two to three years) plug migration. Flat mesh migration is uncommon.

There are several reports of mesh migration after hiatal hernia and incisional hernia repair<sup>489</sup>.

Up to now, there is no polymer or no mesh construction known that is free from the risk of migration if placed in a setting with tensile forces.

A 2015 MRI-based study of mesh migration at three months following TAPP did not detect any substantial change in mesh location<sup>422</sup>.

### *Mesh rejection reactions*

#### **Introduction**

While it is true that hernia meshes induce innate immunological reactions, there is no strong evidence of adaptive immunological reaction i.e. leading to allergic reactions. If so-called mesh “rejection” seems to be occurring, a bacterial infection should be suspected.

#### **Key question**

**KQ10.f** Do mesh polymers elicit rejection reactions?

#### **Statement**

<i>Statement</i>	There is no evidence of true immunologically-based rejection of current synthetic mesh materials.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
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#### **Evidence in Literature**

In the medical literature, there is no human study of the immunogenicity of hernia mesh polymers. Some animal studies do exist, only one demonstrating antibodies against polyester textiles in rats<sup>490</sup>. There are no reports of detectable B-cell or T-cell responses to mesh of any type. In light of current knowledge, there is no need to consider allergic reactions to mesh.

Notably, only a few polymers (e.g. PVDF) can be used without additives and these are supplemented with color particles. It may be that some of these adjuvants might stimulate an allergic or autoimmune syndrome in some patients. However, this has not been reported as of this chapter's writing.

## *Mesh degradation*

### **Introduction**

Degradation here refers to complete or partial fragmentation (after placement in living tissue) of a non-absorbable polymer used for hernia mesh fiber construction (e.g. ePTFE, polyester, polypropylene, and polyvinylidene fluoride). Over time, most polymers do show alteration or degradation of their polymeric structure. These changes may become clinically relevant when mechanical loading occurs. It may be prudent to assume that hernia mesh implant instability can occur after several decades.

### **Key Question**

**KQ10.g** Does mesh degradation occur?

### **Statements**

none

### **Evidence in Literature**

Under electron microscopy, human mesh explants (polyester, polypropylene or PTFE) all show signs of degradation<sup>421,491–495</sup>. PVDF has the highest resistance to degradation<sup>496</sup>. Local infection or exposure to bodily fluids and cells can accelerate mesh degradation<sup>497</sup>.

Several investigators have studied textile structure resistance during repetitive loading in-vitro and have found rapid and irreversible deformation of the textile structure<sup>498–500</sup>. The clinical relevance of this finding is unknown.

### *Best mesh?*

### **Introduction**

Because of human anatomy and physiology, mesh must conform to a certain structure and stability profile. Mesh construction requirements include: strength sufficient to reinforce the repair, “stretchability,” elasticity, ability to integrate into tissues without forming blocking scar, a low risk of precipitating chronic inflammation, and a low risk of bacterial adherence.

Although postoperative complications may occur due to poor surgical technique or patient-specific risk factors, the risk of complications may be increased by the use of a poorly-designed mesh. Mesh selection is therefore an important factor to consider if one wishes to optimize surgical outcomes.

### **Key Question**

**KQ10.h** Which mesh options—in structure and stability—should be considered?

## Statements

None

## Evidence in Literature

A single perfect mesh, meeting all mechanical and biological demands for all patients and procedures, does not exist.

Various factors may impact mesh-related complications<sup>420,498–511</sup>. These factors (see bulleted table below) have been identified from: human anatomy studies, studies of mesh-related failures, numerous preclinical tests in animal species, and in-vitro tests.

- Material reduction can decrease mesh-related complication risk; larger pore flat meshes have a lower risk of mesh-related complications than do small pore flat meshes (see LWM material above).
- A tensile strength of more than 16 N/cm is unnecessary for mesh used in groin hernia repair<sup>504,508,509</sup>.
- Shrinkage and stiffness of flexible mesh is affected by scar tissue. Smaller inter-filament distances and pores have an increased risk of bridging by scar tissue<sup>420,510</sup>.
- For mechanical stress, mesh deformation lengthwise is linked to pore-size reduction. Therefore, prevention of pore collapse to avoid bridging scars requires high structural load stability of the textile construction<sup>378,512–516</sup>.
- Plugs, when compared with flat meshes, have higher risks of extensive fibrosis and are more likely to stimulate an intense inflammatory reaction, thereby resulting in nonconforming biomechanical properties<sup>420,512</sup>.

Since several mesh-related complications manifest in a delayed manner (occurrence after years or even decades), some complication rates are currently underestimated. Long-term registry data may provide a more accurate picture of mesh-related complications.

Current data on physiological biomechanical requirements are flawed and only provide rough estimates of mesh's mechanical characteristics. In the groin, the tensile strength of mesh need not be higher than 16 N/cm, but it is unknown whether a minimum strength requirement exists.

Characterization of in-vivo mesh materials must account for functional and biological outcomes. Any attempt to stratify meshes' impact on surgical outcomes has to consider the complex

interplay between the polymer, the textile structure with fiber, the total amount of material, the porosity, the configuration of textile bindings, the implant location, and the mechanical strain placed upon the implant. None of these parameters in isolation are able to predict the inflammatory and fibrotic tissue response and classify meshes across all mesh-related complications.

One mesh classification focuses on the risk for mesh infection and separates meshes with pores  $< 75 \mu\text{m}$  (high risk for infection) from those with pores  $> 75 \mu\text{m}$  (low risk)<sup>501</sup>.

Another classification stratifies by risk for fibrotic bridging (defined as pores completely filled by scar), separating large-pore meshes ( $> 1 \text{ mm}$ , effective porosity  $> 0\%$ ) from small-pore meshes ( $< 1 \text{ mm}$ , effective porosity  $= 0\%$ )<sup>420</sup>.

Small-pore constructions have a high risk for fibrotic bridging whereas large-pore constructions have a lower risk. Importantly, pore size measurement is not accurate if done using only one dimension (just length or just width for example).

A technique does exist however to provide an accurate measurement of pore sizes which do avoid fibrotic bridging<sup>502</sup>. It is our strong opinion that studies using only the designation “small pore” or “large pore” have inherent limitations unless they use the technique described by Mühl et al<sup>502</sup> or an equivalent.

Sub-grouping of meshes by weight has been proposed<sup>503,504</sup>. However, meshes of similar weights can be made of different polymers (PVDF is much heavier than polypropylene), can contain smaller fibers and smaller pores, or can contain thicker fibers and larger pores. All these modifications will result in substantially different biological responses (e.g.,<sup>517</sup>). Therefore, mesh weight alone is not sufficient to predict complications.

Due to manufacturing process differences, textile meshes often have considerable anisotropy with different mechanical properties when stressed vertically or horizontally. Therefore, any measurement of strength and elasticity is strongly affected by the setting of the test procedure (e.g., tensile strength tested on mesh strips or by puncture test, various width of the mesh sample, or distinct directions of the mesh fibers in the test unit). As a result, the strength and elasticity of anisotropic meshes cannot be expressed as a single number<sup>504,511</sup>.

*Mesh risk for carcinogenesis*

## **Introduction**

If mesh implants confer a heightened carcinogenic risk, this will severely affect the risk/benefit ratio of mesh-based surgery.

## **Key question**

**KQ10.i** Is there a risk for carcinogenesis at meshes' interfaces?

## Statements

none

## Evidence in Literature

It is clear that foreign bodies like textile mesh can induce malignancies in rodents, particularly in rats<sup>518-523</sup>. Thankfully though, there is no evidence that hernia meshes measurably increase the malignant transformation rate in humans.

There are however two reports worthy of mention. In one, abdominal wall fibromatosis developed in two patients after laparoscopic mesh placement<sup>524</sup>. In another, aggressive squamous cell cancer occurred at the site of chronic mesh infection, and this may be regarded as mesh-induced cell proliferation/malignancy<sup>525</sup>.

In 2000, The International Agency for Research on Cancer stated that “Polymeric implants prepared as thin smooth films (with the exception of poly(glycolic acid)) are *possibly carcinogenic to humans (Group 2B)*”<sup>526</sup>.

There is inadequate evidence in humans for the carcinogenicity of non-metallic implants other than those made of silicone.

In summary, there is no evidence that meshes meaningfully increase carcinogenesis risk. Thus, the risk for mesh-related carcinogenesis need not be considered in the risk/benefit evaluation of a mesh repair.

*Patient age risks*

## Introduction

Patient age is often a critical consideration in many surgical procedures. Many IH surgery patients have years of productive life ahead of them. Therefore, it is important to know if patient age affects the complication risk profile.

## Key Question

**KQ10.j** Is there an age-associated risk for mesh-related complications?

## Statements

none

## Evidence in Literature

There are no adequately age-adjusted studies of complications following mesh-based IH repair. Also, no data exist on length of implantation period as an independent risk factor for complications.

There are however, registry data indicating that increased patient age (especially > 65 years) is a risk factor for complications<sup>79</sup>.

Several studies indicate that complications following mesh repair can occur after years. Mesh explantation, for example, usually occurs two to three years after implantation<sup>420,527</sup>.

National registry data analyses usually show a nearly linear increase in reoperation rate, reflecting a permanent risk with an almost constant incidence over time<sup>79,528,529</sup>. It is therefore, reasonable and logical to think that lifetime risk of complications will be increased for younger patients, though there are no data confirming this. A long implantation period should be considered a mesh-related complication risk factor when considering the risk/benefit ratio of mesh repair.

### *Mesh shrinkage*

## Introduction

Shrinkage of the mesh —caused mainly by collagen shortening— results in physiological wound contraction. This phenomenon, in turn, is related to scar tissue amount, influenced by surgery-induced local tissue trauma and patient-specific responses to tissue injury.

## Key Question

**KQ10.k** Does mesh shrinkage occur, and if so, to what extent?

## Combined Statements for Key Questions g to l

Statement	Specific contraindications for flat meshes made from polymers are not known, even when adjusting for age. However, the risks of mesh-related complications increase with increasing implantation duration.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Mesh shrinkage of at least 20% has to be accounted for depending on mesh structure and host tissue response.	
	There is no evidence of mesh-related carcinogenesis.	

## Evidence in Literature

It is known that certain patients develop enhanced scar formation and/or marked wound contraction, whereas others do not. It is also known that textile meshes induce a chronic foreign body reaction with local inflammation and fibrosis (see KQ10d). In the case of small pore meshes this reaction can bridge the entire inter-filament distance<sup>420,512</sup>. Thus, small pore meshes develop



increased shrinkage in the area of surgical trauma. Mesh infection, with its resultant inflammation and increased fibrosis, exacerbates this process and results in even more shrinkage.

Of note, mesh polymers themselves do not shrink, but the textile itself shortens, pulled together by the contracting scar<sup>420</sup>. Thick and stiff filaments in a rigid textile implant resist shrinkage more than large pore meshes and offer flexibility adapted to surrounding tissues<sup>378</sup>.

Mesh shrinkage varies markedly. For plugs, a volume reduction due to shrinkage of up to 90% has been reported with the formation of a so-called meshoma<sup>530</sup>. It is reasonable that mesh area shrinkage of greater than 50% increases postoperative risks and should be avoided if possible by minimizing surgical trauma and/or foreign body reaction<sup>530–545</sup>.

Studies of MRI-visible large-pore PVDF mesh report an up to 20% reduction in mesh surface area indicating a shortening across length and width of about 10%<sup>546</sup>. These studies confirm the results of a 2011 trial performed with digital computed radiographs and metal clips at a Lichtenstein mesh border<sup>533</sup>.

However, today these changes are small in relation to the accuracy of the CT/MRI measurements, and thus need to be confirmed by further studies.

## **Chapter 11 Mesh Fixation**

R.H. Fortelny, D.L. Sanders and A. Montgomery

### **Introduction**

Synthetic mesh fixation in both open and endo/laparoscopic hernia repair involves a consideration of the strength of fixation versus the risk of trauma to local tissues and nerve damage through entrapment. Mesh fixation complications include: mesh migration, adhesions, erosion and hernia recurrence<sup>547–551</sup>, “meshoma” formation<sup>552</sup>, tack hernias<sup>553</sup>, chronic pain<sup>554–559</sup>, and infection<sup>560,561</sup>. A number of RCTs—also summarized in meta-analyses—have compared different mesh fixation methods in both open and laparo-endoscopic IH repair. Various mesh fixation methods exist including: tacks, staples, self-fixing, fibrin sealants (FSs), glues and sutures. However, consensus does not exist about a “best” fixation method so methods used are based on surgeons’ preferences. Evidence that a particular fixation method improves patient-based or surgical outcome measures may have a significant impact on clinical practice. The material below covers two topics: fixation in open hernia repair and fixation in laparo-endoscopic hernia repair. Special patient-related circumstances are also highlighted.

### **Open inguinal/femoral primary hernia repair**

#### **Key question**

#### **KQ11.a**

Which fixation methods are appropriate in primary open anterior mesh inguinal and femoral hernia repairs in those over 18 years of age?

#### Statement and Recommendation

<i>Statement</i>	In open anterior mesh groin hernia repairs there are no differences in recurrence, surgical site infection rates or length of stay between different fixation methods. Fixation with glue (fibrin sealant or cyanoacrylate) may reduce early postoperative and chronic pain.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Recommendation</i>	Atraumatic mesh fixation in open inguinal hernia repair techniques is suggested to reduce early postoperative pain.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <b>Weak</b>

#### Evidence in Literature

A search using the PICO criteria shown in the addendum yielded eight systematic reviews on the subject of mesh fixation in primary open IH repair<sup>174,176,178,562–567</sup>. Seven of these reviews assessed IH repair using an anterior mesh repair while one assessed both open anterior and laparoscopic repairs (Table 1).

#### Systematic Reviews on Fixation Methods - 12 RCTs

##### Fixation Methods – Systematic Review

Mesh fixation methods were assessed in one moderate-quality systematic review of 12 RCTs involving 1,992 primary IH repairs<sup>567</sup>. Data heterogeneity precluded performance of a meta-analysis. Four studies compared n-Butyl-2 Cyanoacrylate (NB2C) glues to sutures, two compared self-fixing meshes to sutures, four compared fibrin sealant to sutures, one compared tacks to sutures, and one compared absorbable sutures to non-absorbable sutures. Per GRADE guidelines, none of the RCTs were rated as high quality (Table 2). The most common reasons for low or very low study grading were: lack of power calculations, small subject numbers, short follow-up periods, and poorly-matched groups (for age, hernia size and comorbidities).

##### *Recurrence*

Thirteen of these 26 recurrences were reported in one study with a five-year follow-up utilizing NB2C glue<sup>568</sup>. There were no significantly different recurrence rates found between fixation methods in any of the RCTs.

### *Infection rates*

Surgical site infection (SSI) data were included in eight of the studies. No study distinguished between superficial and deep SSI. SSI diagnostic criteria were infrequently documented. Overall infection rates ranged from 0% to 3.5%; and infection resulted in three mesh explantations. Choice of fixation method did not result in any significant difference in infection rates.

### *Chronic pain*

All studies included chronic pain data. Most defined chronic pain as pain persisting beyond three months but a range of definitions was used (range 3-12 months). One study did not include a chronic pain definition<sup>569</sup>. Five studies measured chronic pain incidence at three months<sup>568,570-573</sup>, two only at six months<sup>169,359</sup>, and three only at one year<sup>172,574,575</sup>. One study used a composite endpoint of pain, numbness, and groin discomfort at one year (at six months if one-year data were not available).

Overall, chronic pain rates ranged from 0% to 36.3%. The combined chronic pain rates for mesh fixation of various types were: 14.7% for sutures, 7.6% for NB2C glue, 3.7% for FS, and 18.2% for self-fixing meshes.

Nine studies reported no significant difference in chronic pain between fixation methods. Three identified a significant reduction with NB2C glue<sup>572</sup> or FS<sup>359,576</sup> compared with sutures. One RCT of moderate quality randomized 316 patients to either Tisseel®/ Tissucol® or 2/0 Prolene® sutures and reported a significant reduction in chronic pain at six months (defined as VAS > 3) with FS versus sutures (8.1% vs. 14.8%,  $p=0.035$ )<sup>576</sup>. A very low quality RCT of 148 patients randomized to either Quixil® FS fixation of lightweight mesh or Vicryl® suture fixation of a heavyweight mesh found chronic pain at six-month follow-up (determined by mean VAS scores) was lower in the FS/lightweight mesh group (0% vs. 7.8%,  $p<0.001$ )<sup>359</sup>.

### *Pain within the first week postoperatively*

Six RCTs reported on pain in the first postoperative week. Two studies noted significantly lower mean VAS scores at one or more assessment times within week one, with FS<sup>359</sup>, NB2C glue<sup>571</sup>, or self-fixing mesh<sup>169</sup> compared with suture fixation. Two RCTs reported no significant difference in mean VAS scores between fixation methods<sup>573,576</sup>. A significant reduction in postoperative pain within the first 24 hours was observed with non-suture compared with suture fixation in three RCTs. The mean difference in VAS scores was 0.80 ( $p<0.001$ ) with FS<sup>359</sup>, 1.44 ( $p=0.031$ ) with self-fixing mesh<sup>169</sup>, and 0.90 ( $p=0.003$ ) with NB2C glue<sup>571</sup>. Notably, all these RCTs were graded as very low quality because of small patient numbers or confounding variables. Furthermore, only one of these studies (FS versus suture fixation) showed a sustained difference in pain scores one week postoperatively<sup>359</sup>.

### *Operative time*

Operative times were reported in 10 RCTs. Five reported significantly shorter operative times with non-suture mesh fixation. Two of these studies compared self-fixing meshes with suture fixation and reported nine-minute ( $p=0.01$ )<sup>172</sup> and 12-minute ( $p=0.008$ )<sup>169</sup> reductions in mean operative times. Similarly, reduced mean operative times of six minutes were reported in two studies comparing NB2C glue with suture fixation<sup>568,572</sup>. A reduced mean operative time of 18 minutes ( $p<0.001$ ) was reported in one study comparing FS with suture fixation<sup>359</sup>.

### *Hospital stay*

Three meta-analyses, all published in 2013—two of moderate<sup>562,563</sup> and one of low quality<sup>564</sup> — have examined glue versus suture fixation in open anterior mesh IH repair. Despite methodological differences, all three meta-analyses reported an approximate two to three minute shorter operative time with glue compared with sutures. The clinical significance of this small difference is debatable. One of the meta-analyses reported no difference in other outcomes including chronic pain (RR, 1.60; 95% CI, 0.78, 3.28;  $z = 1.28$ ;  $p=0.20$ ), while the other two reported reduced postoperative pain (RR 0.46, 95%CI 0.22-0.97;  $p=0.01$ ) and chronic pain (RR 0.51, 95 % CI 0.31 to 0.87;  $p=0.01$ ). These differences are remarkable, given that the articles were all published within the same year, and may reflect selection criteria for included studies and the meta-analysis methods used.

Three additional meta-analyses, all published in 2013/14, and all of low quality, have examined self-fixing meshes compared with suture fixation in open anterior mesh IH repair<sup>174,176,178</sup>. All reviewed data from the same primary studies of 1,353 patients. No inter-group differences in recurrence, chronic pain or SSI were found. However, shorter operative times (range of one to nine minutes) were noted with self-fixing mesh.

## **Laparo-endoscopic Inguinal/Femoral Primary Hernia Repair**

### **Key Questions**

**KQ11.b** Is mesh fixation necessary in endoscopic TEP inguinal/femoral hernia repair in adults?

**KQ11.c** Are there specific indications for mesh fixation in endoscopic TEP inguinal/femoral hernia repair in adults?

**KQ11.d** Is mesh fixation ever recommended in laparoscopic TAPP inguinal/femoral hernia repair in adults?

**KQ11.e** If using mesh fixation, what types should be used in TEP and TAPP inguinal/femoral hernia repairs?

## Statements and Recommendation

<i>Statement</i>	In almost all cases, any type of mesh fixation in TEP repair is unnecessary.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Statement</i>	Atraumatic mesh fixation techniques are favored to reduce early postoperative pain.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>Recommendation</i>	Traumatic mesh fixation (tackers) is recommended in patients with large direct hernias (M3-EHS classification) undergoing TAPP or TEP to reduce recurrence risk.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <b>Strong</b> <b>*Upgraded</b>

## Evidence in Literature

Using the PICO criteria shown in Appendix 2, Pubmed and Cochrane databases were systematically searched, yielding a total of 67 papers of which 34 were included after applying strict inclusion (SIGN) criteria. Following the GRADE approach for Guidelines the reviews by Schäfer et al<sup>577</sup>, Morales-Conde<sup>578</sup> and Fortelny<sup>565</sup> were excluded. Of the 34 included papers, five are systematic reviews/meta-analyses<sup>566,579–582</sup>, 17 are RCTs<sup>583–599</sup>, and 12 are case control studies (CCS)<sup>402,596–608</sup> (Table 3).

## Fixation Versus Non-fixation in TEP and TAPP

The systematic review and meta-analyses<sup>580–582</sup>—all judged to be of moderate quality per GRADE guidelines—revealed no significant differences in the rates of recurrence or postoperative pain between permanent tack fixation and non-fixation in either TEP or TAPP

### Recurrence

For TEP repair, the results of six RCTs<sup>588,590,594,596,598,599</sup>, three CCSs<sup>588,607,608</sup>, and two meta-analyses<sup>581,582</sup> demonstrate no significant risk of recurrence following mesh non-fixation.

For TAPP repair, one RCT of moderate quality, comparing tack-fixation with non-fixation demonstrated no significant difference in recurrence risk (Table 4).

Notably, the RCTs cited above contain only limited information on hernia-defect size and type. This is especially true regarding the percentage of large direct hernias (type M3, EHS-classification).

Based on the results of a multivariate analysis of 11,230 cases from a Herniated registry study<sup>609</sup> a significant risk of recurrence is found not only in the group of non-fixation in case of direct hernias but also for combined hernias (combined versus medial: OR 1.137 (95 % CI 0.656 - 1.970; lateral versus medial: OR 0.463 (95 % CI 0.303-0.707);  $p < 0.001$ ).

#### *Acute and chronic pain*

The three meta-analyses<sup>580-582</sup> of eight RCTs revealed no significant differences in acute and chronic postoperative pain<sup>581,582,588</sup>. Of the RCTs studying TEP repair<sup>588,590,594,596,598</sup> only one<sup>590</sup> detected significantly less acute and chronic pain in the non-fixation group. The sole RCT on TAPP repair<sup>590</sup> showed significantly less acute and chronic pain in the non-fixation group. Of three case control TEP repair studies<sup>607,608,610</sup>, only one<sup>610</sup> revealed a significantly lower rate of acute postoperative pain in the non-fixation group (Table 5).

Reporting on preoperative pain is one of the greatest shortcomings of almost all studies. This information is essential to identify patients at high risk for postoperative chronic pain. Furthermore, the pain assessment within the different studies displays significant heterogeneity.

The Swedish Hernia Register study about the impact of mesh fixation on chronic pain in TEP in primary IH repair in men enrolled 1,110 patients. It compared permanent fixation (PF) with no fixation (NF) or non-permanent fixation (NPF)<sup>611</sup> and revealed no difference regarding the primary endpoint of pain ( $p < 0.462$ ) using Inguinal Pain Questionnaire and SF-36 subscales as well as no difference between PF- and NF-groups including subgroups of medial hernias during a 7.5 year follow-up.

#### *Operative time*

In several meta-analyses, including data from both TEP- and TAPP-RCTs, no significant differences in operative times have been reported<sup>330,580,581,588,590,594,596,598</sup>. A separate meta-analysis including three TEP-RCTs<sup>594,596,607</sup> revealed a significant reduction in operative time when mesh non-fixation was used.

#### *Surgical site infection*

Two RCTs<sup>596,597</sup> and one CCS<sup>608</sup> on SSI demonstrated no difference between fixation and non-fixation groups.

### **Permanent Versus Non-permanent Fixation (staple/tack vs glue) in TEP Repair**

#### *Recurrence*

Two meta-analyses of moderate quality<sup>566,579</sup> found no significant recurrence rate difference between staple and glue fixation methods. The results of three RCTs<sup>583,587,595</sup> included in the meta-analyses<sup>566</sup>, as well as another four CCSs<sup>600,605,606,612</sup> confirmed these findings (Table 6).

In addition to the meta-analyses and RCTs, a recently published study from the Danish Hernia Database included 1,535 patients and detected no significant difference using cox regression analysis (hazard ratio 0.8; 95 % CI (0.5–1.2))<sup>613</sup> in long-term reoperation rates and clinical recurrences (median follow-up time of 31 months) in patients undergoing TAPP IH repair with mesh fixation by fibrin sealant compared to tacks.

#### *Acute and chronic pain*

One systematic review<sup>566</sup> analyzed only RCTs including TAPP repairs<sup>589,592,593</sup> and one TEP repair<sup>595</sup>. Concerning acute pain, the review analysis detected no significant difference between staple and fibrin sealant groups. A significant difference was found however in the incidence of chronic pain favoring the fibrin sealant group. Another review<sup>579</sup> included one RCT<sup>595</sup> and three CCSs<sup>605,606,612</sup> and reported on chronic pain incidence only. Both reviews<sup>566,579</sup> revealed significant advantages of glue fixation in lessening the incidence of chronic pain. However, as noted, only one RCT<sup>595</sup> was included in these two systematic reviews. In total, three RCTs have been published<sup>583,587,595</sup> and detected no significant difference in chronic pain when glue was compared to staple fixation. Three case control trials<sup>605,606,612</sup> however found significantly less chronic pain in the glue fixation group (Table 7).

#### *Operative time*

Two systematic reviews<sup>566,579</sup> failed to demonstrate an operative time difference between groups undergoing different fixation methods. Similarly, one RCT<sup>595</sup> and one case control trial<sup>612</sup> also noted no significant difference although a different case control trial<sup>600</sup> revealed longer operative times in the glue group.

#### *Surgical site infection*

SSI rates were not significantly impacted by different fixation methods across a systematic review<sup>579</sup>, two RCTs<sup>583,595</sup> and two case control trials<sup>605,606</sup> that examined the subject.

### **Permanent Versus Non-permanent Fixation (staple/tack vs glue) in TAPP Repair**

#### *Recurrence*

One meta-analysis of moderate quality that included only RCTs<sup>589,591–593</sup> specifically addressed glue versus staple fixation in TAPP repair<sup>566</sup> and reported no significant inter-group difference (Table 6). The results of six RCTs<sup>584,586,589,591–593</sup> and three case control trials<sup>402,601,603</sup> confirmed this finding.

### *Acute and chronic pain*

One systematic review<sup>566</sup> that included four RCTs<sup>589,591–593</sup> found no significant difference in acute postoperative pain between glue- and staple-fixation groups. However, five RCTs<sup>584,586,591–593</sup> and three CCSs<sup>402,601,603</sup> found significantly less acute pain after glue versus staple fixation (Table 7).

One systematic review<sup>566</sup> revealed a significantly higher incidence of chronic pain when the staple group was compared with the glue group. In contrast, three of six RCTs<sup>586,589,591</sup> and two of three case control trials<sup>402,603</sup> reported no significant difference (Table 7). An important criticism of the systematic review<sup>566</sup> was that it included one-month follow-up data from one study as chronic pain data. Another study<sup>589</sup> showing no difference was excluded for unknown reasons.

### *Operative time*

No significant difference was seen between fixation methods in the systematic review<sup>566</sup>.

### *Surgical site infection*

Two RCTs<sup>586,593</sup> and two CCSs<sup>601,603</sup> reported on surgical site infection and no significant difference in SSI risk was detected between fixation methods.

## **Self-fixing Mesh in TAPP**

One moderate-quality RCT compared self-fixing mesh to glue fixation in TAPP repair<sup>588</sup>. Short-term follow-up at three months found no hernia recurrences and no significant differences in postoperative pain between groups. A CCS had similar results<sup>602</sup>.

## **Summary**

In open primary inguinal/femoral hernia repair beyond the use of sutures (non- or late-resorbable) for mesh fixation new atraumatic devices (e.g. fibrin glue, cyanoacrylate, self-fixating meshes) are safe in terms of recurrence and reduce the risk of acute and chronic postoperative pain. The use of self-fixing meshes is feasible in all hernia types and sizes without raising the risk for recurrence, whereas glue fixation in the Lichtenstein technique can be performed in hernias limited to MII or LII types (EHS classification).

In TEP and TAPP inguinal/femoral hernia repair non-fixation of mesh is recommended in almost all hernia types except large medial defects (M3 EHS classification) where mesh fixation is recommended. If fixation is used, atraumatic fixation techniques (fibrin glue, cyanoacrylate) should be considered to minimize the risk of acute postoperative pain.



## Chapter 12 Antibiotic Prophylaxis

A. Montgomery, Th.J. Aufenacker and J. Bingener

### Introduction

Prophylactic antibiotics in inguinal herniorrhaphies are intended to prevent infections, which is particularly important when prosthetic material is used. However, unwarranted antibiotic use may create problems, notably patient allergies, *C. difficile* infection, bacterial resistance and increased costs, amongst others. Antibiotic use is widely accepted in patients with risk factors and in contaminated and infected conditions. However, prophylactic antibiotic use should be questioned under clean conditions in patients with limited risk factors for infection. Current evidence is presented.

### Key Questions

**KQ12.a** Are prophylactic antibiotics indicated in open mesh repair in an average-risk patient in a low-risk environment?

**KQ12.b** Are prophylactic antibiotics indicated in open mesh repair in a high-risk patient in a low-risk environment?

**KQ12.c** Are prophylactic antibiotics indicated in open mesh repair in any patient in a high-risk environment?

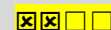
**KQ12.d** Are prophylactic antibiotics indicated in laparoscopic repair in any patient in any risk environment?

### Recommendations

<b>Recommendation</b>	In open mesh repair, administration of antibiotic prophylaxis in average-risk patients in a low-risk environment is not recommended.	☒☒☒☒	Strong
<b>Recommendation</b>	Administration of antibiotic prophylaxis in open mesh repair in high-risk patients in a low-risk environment is suggested.	☒☐☐☐	Weak
<b>Recommendation</b>	Administration of antibiotic prophylaxis in open mesh repair in any patient in a high-risk environment is recommended.	☒☒☒☒	Strong

**Recommendation**

In laparo-endoscopic repair in any patient in any risk environment, antibiotic prophylaxis is not recommended.

**Strong****\*upgraded**

## Evidence in Literature

The latest Cochrane meta-analysis, encompassing 11 RCTs, was published in 2012<sup>614</sup>. Additional relevant and crucial data were abstracted from papers published in 2013 and 2014<sup>4,615,616</sup>. In total, 17 RCTs involving 5,709 patients were included to formulate the recommendations. Eight of the articles included in this analysis are of high or moderate quality while the rest are of low or very low quality.

Difficulties in data interpretation stem from the fact that inclusion criteria vary broadly across the RCTs. This variation encompasses patient risk factors (e.g. immunosuppression, diabetes, heart failure), hernia characteristics (e.g. primary, bilateral, recurrent), and operative or postoperative interventions (e.g. wound infection incidence, hair shaving, drain use, seroma puncture, wound infection incidence). The current analysis accounts for this variation and defines *average-risk patients* as those with primary hernias and minimal individual or operative risk factors. Of note, only elective operations are included in the 17 RCTs. High-risk patients—with comorbidities like diabetes—are only referenced in two of the 17 articles, representing 8.3% of all patients<sup>617,618</sup>.

There is a potential risk of resistance to the prophylactic antibiotic given varying between countries and different settings. This problem is not highlighted in any study.

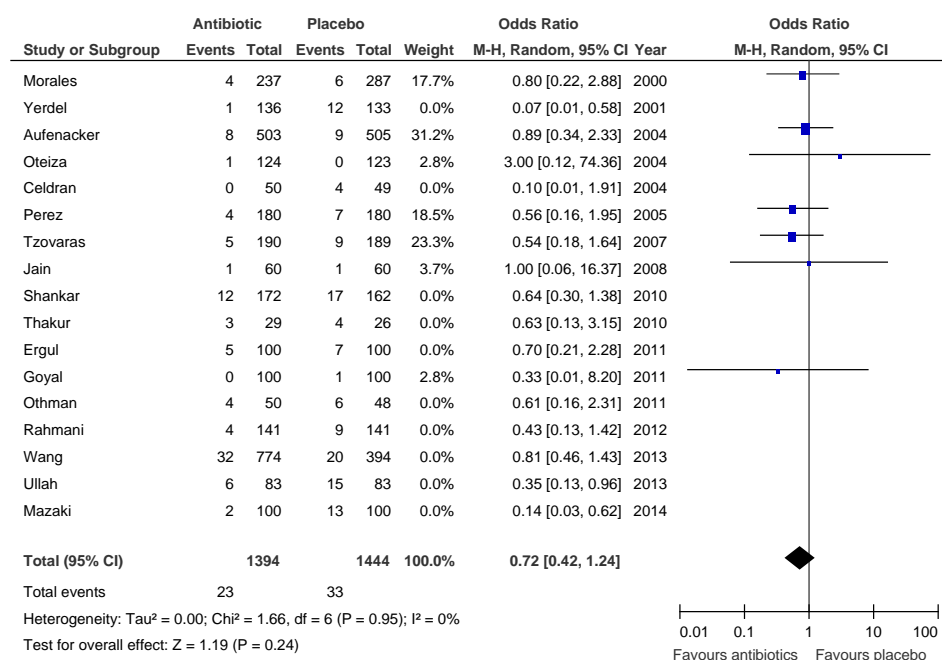
The wound infection rates in the placebo groups varied widely, from 0% to 18%, likely reflecting the basal wound infection rates in the study population. High wound infection rates were noted in studies from Pakistan, Turkey, Japan and parts of India and Spain, and may reflect local differences in perioperative and operative practice for hygiene protocols.

Highly regarded guidelines and expert opinions hold that a less than 5% wound infection rate in the placebo group defines a *low-risk environment*. This cut off has been used for this analysis<sup>4,615</sup>. Accordingly, the 17 RCTs have been divided into those involving low- and high-risk environments and analyzed for potential benefit of antibiotic prophylaxis. A total of seven studies with 2,838 patients comprise the low-risk environment group and ten studies with 2,871 patients make up the high-risk environment group.

The overall meta-analysis results of the RCT's have to be corrected for a large clinical diversity (inclusion criteria variations regarding diabetes and recurrent hernia) and methodological diversity (surgical variations: drain use, average surgical time, seroma aspiration, timing of shaving) by using the random effect model.

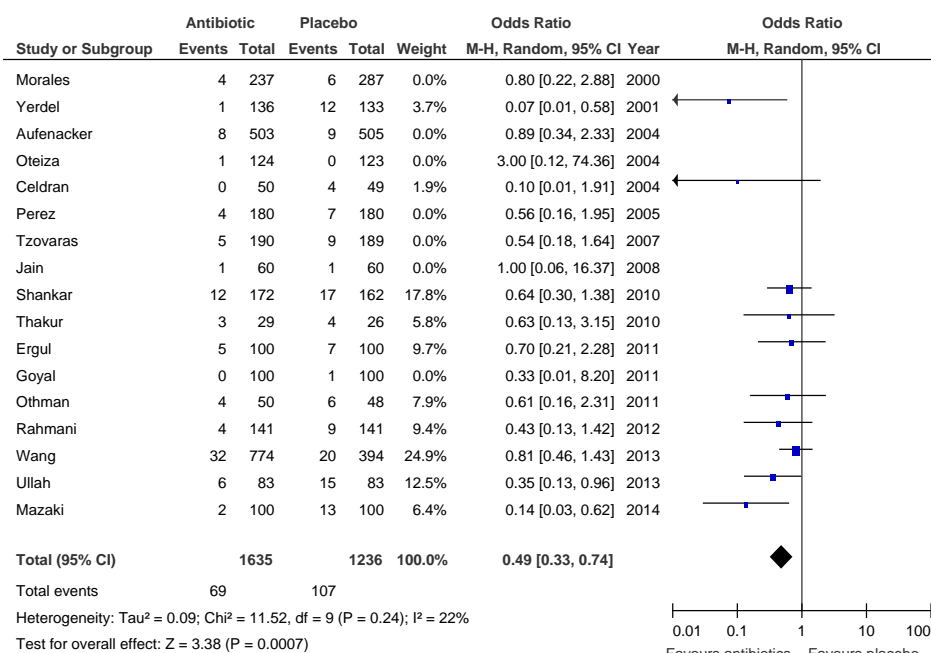
Wound infections occurred in 2.3% (33/1,444) of the low-risk environment placebo group and 1.6% (23/1,394) of the prophylaxis group, confirming a lack of evidence for prophylactic antibiotic benefit in the low-risk environment group (OR 0,72; 95 % CI 0,42-1,24; NNT 158)

Figure 1. Nine (0.3%) deep surgical site infections occurred, with no difference between placebo and prophylaxis groups.



**Figure 1** Pooled data of 7 studies in low-risk environments (<5% wound infection) on the use of antibiotic prophylaxis in the prevention of wound infection after mesh inguinal repair

Wound infection rates in the high-risk environment group were 8.7% (107/1,236) in the placebo group and 4.2% (69/1,635) in the prophylactic antibiotics group showing a clear benefit of antibiotic prophylaxis in this setting (OR 0.49; 95 % CI 0.33-0.74, NNT 24) (Figure 2). Fourteen (0.45%) patients developed deep surgical site infections with no difference between placebo and antibiotic prophylaxis.



**Figure 2.** Pooled data of 10 studies on the use of antibiotic prophylaxis in the prevention of wound infection in centers with a high incidence (>5%) of wound infection after mesh inguinal repair

The 2014 annual report of the Swedish Inguinal Hernia Register, which covers 95% of all hernia operations, revealed that 5.6% out of the 14,053 patients operated upon received antibiotic prophylaxis. Primarily high-risk patients as defined by national guidelines received antibiotics. Postoperative infection rates were reported as 1.2% in males and 1.5% in females<sup>619</sup>.

Germany's national register "HerniaMed" reported on the use of antibiotic prophylaxis<sup>620</sup> enrolling 85,000 patients (57% laparo-endoscopic operations). Antibiotic prophylaxis was administered in 70% of patients and infection was seen in 0.2% in the laparo-endoscopic group and 0.6% in the open surgery group. In a multivariate analysis on wound healing the OR was 0.318 (CI 0.23-0.44) comparing laparo-endoscopic to open operation. It is concluded that endoscopic repair per se has such a high benefit in reducing wound infections, that the administration of antibiotic prophylaxis is not necessary. For open repair it was concluded that there was a benefit for antibiotic prophylaxis, but this summary statement did not account for factors like: reason for open or endoscopic repair, use of drains, timing of shaving, seroma aspiration, long operative time and bilateral repair. Due to the low incidence of infection, the number needed to treat was 323 to prevent one infection. Therefore, the clinical relevance of this conclusion can be argued.

There is only one small, low-quality RCT demonstrating no wound infections in any group in laparo-endoscopic IH repairs. Data from large patient cohorts in national registers do not support the use of antibiotic prophylaxis in these patients<sup>620,621</sup>.

*Special circumstances for antibiotic use*

There are very limited data on high-risk patients in a low-risk environment. Two small studies address this issue but only include a few patients who might be considered to have any increased risk for postoperative surgical site infection. A consensus does not exist on what constitutes a high-risk patient in a low-risk environment for hernia surgery. However, common surgical practice includes antibiotic prophylaxis for increased-risk patients and these currently also include those undergoing IH repair. This is an area ripe for further studies.

Univariate and multivariate analysis of individual trials reveals an increased risk of wound infections in patients undergoing bilateral open hernia repairs and recurrent hernia repairs. This is likely due to increased operative time. There are insufficient data to draw conclusions on antibiotic prophylaxis for high-risk patients with diabetes or immunosuppression.

In a high-risk environment (defined by a >5% incidence of wound infection) there is a significant benefit of antibiotic prophylaxis. Therefore, in institutions with high wound infection rates, antibiotic prophylaxis is highly recommended. Furthermore, in these institutions the general risk factors influencing wound infections should be checked (like hygiene routines, shaving on the day before surgery and seroma aspiration, etc.)<sup>622</sup>.

## **Chapter 13 Anesthesia**

A.R. Wijsmuller and P. Nordin

### **Key Question**

**KQ13.a** Does local anesthesia influence outcomes after open repair of reducible inguinal hernia when compared with general or regional anesthesia?

### **Introduction**

General, regional and local anesthetic techniques are used to facilitate open IH surgery. Regional anesthesia can be performed via epidural, spinal and paravertebral routes. However, a discussion of paravertebral anesthesia is not included in this section since limited data are available on this technique.

The ideal anesthetic technique: provides good perioperative and postoperative analgesia, produces optimal operating conditions by immobility, is associated with few complications, facilitates early patient discharge, and is cost effective. The EHS guidelines on IH treatment recommends that local anesthesia be considered for all adult patients with primary reducible unilateral IHS.

## Statements and Recommendations

<i>Statement</i>	When compared with general anesthesia, local anesthesia is associated with faster mobilization, earlier hospital discharge, lower hospital and total healthcare costs, and fewer complications such as urinary retention and early postoperative pain. However, when surgeons inexperienced in its use administer local anesthesia, more hernia recurrences might result.	⊗⊗⊗⊗	
<i>Statement</i>	When compared with regional anesthesia, local anesthesia is associated with earlier hospital discharge, lower hospital and total healthcare costs, and a lower incidence of urinary retention. However, when surgeons inexperienced in its use administer local anesthesia, more hernia recurrences might result.	⊗⊗⊗⊗	
<i>Recommendation</i>	Local anesthesia is recommended for open repair of reducible inguinal hernias provided surgeons experienced in local anesthesia use administer the local anesthetic.	⊗⊗⊗⊗	strong
<i>Recommendation</i>	Correctly performed local anesthesia is suggested to be a good alternative to general or regional anesthesia in patients with severe systemic disease.	⊗⊗□□	weak

## Evidence in Literature

We identified one meta-analysis and five reviews comparing local to general anesthesia<sup>623–628</sup>. Of 17 randomized trials found<sup>629–645</sup>, the most recent are included in the reviews<sup>630,634,643</sup>. SIGN analysis of the 2009 meta-analysis revealed methodological shortcomings<sup>624</sup>. One shortcoming was the performance of a meta-analysis on urinary retention despite heterogeneity between studies. In addition, urinary retention data from the largest RCT comparing general to local anesthesia were omitted. These omitted figures demonstrate a lower incidence of urinary retention after local anesthesia when compared with general anesthesia<sup>643</sup>. A more recent 2012 review did not perform a meta-analysis because of included study design variation<sup>625,628</sup> and found a lower incidence of urinary retention following local anesthesia<sup>628</sup>.

When compared with general anesthesia, local anesthesia is more cost effective when hospital and total healthcare costs are considered<sup>646</sup> and provides earlier patient mobilization and hospital discharge<sup>628</sup>. Although perioperative pain sensation is reported and can sometimes be a reason for conversion to general anesthesia<sup>633</sup>, early postoperative pain seems less in the local anesthesia group<sup>628</sup>. Some randomized studies report no inter-group difference in satisfaction or quality of life with respect to the operation and the first postoperative week<sup>628,629,631</sup>. Others report higher patient satisfaction with the anesthetic technique for patients randomized to local anesthesia<sup>632,634</sup>.

We identified five reviews<sup>623,625–628</sup> and 11 randomized trials<sup>632,634,638,639,643,647–652</sup> comparing local to spinal anesthesia. The most recent meta-analysis, published in 2012<sup>628</sup>, did not include one randomized trial of spinal versus local anesthesia<sup>648</sup>. The authors of this meta-analysis performed an analysis with respect to urinary retention and found a lower incidence of urinary retention in local anesthesia patients<sup>628</sup>. The incidence of reported postoperative pain varies, ranging from no difference to less early postoperative pain after local anesthesia<sup>628</sup>. Two randomized trials reported no differences in postoperative nausea<sup>632,634</sup>. However, the largest randomized trial (with more subjects than the other two trials combined) reported less postoperative nausea in the local anesthetic group<sup>643</sup>. The majority of studies report faster hospital discharge after local anesthesia<sup>628</sup>. Local is more cost effective than spinal anesthesia when hospital and total healthcare expenditures are compared<sup>646</sup>. Crossover rates from local and regional anesthesia to general anesthesia strongly favor local anesthesia (1.9% versus 9.6% respectively)<sup>643</sup>.

Hernia registries provide insights into IH recurrence risks with different anesthetic modalities. A Swedish Hernia Registry analysis of 59,823 patients found that local anesthesia is associated with an increased risk of reoperation for recurrence after primary IH repair<sup>51</sup>. Using local anesthesia as a reference, they reported reoperation relative risks of 0.76 and 0.79 for regional and general anesthesia, respectively. A Danish Hernia Database analysis of 43,123 patients reported an increased reoperation rate after local anesthesia versus general or regional anesthesia after direct—but not indirect—hernia repair<sup>78</sup>. The same database analysis found lower reoperation rates following hernia repair by private hernia surgeons with uniform use of local anesthesia when compared with primary IH repair in general hospitals. They concluded that local anesthesia use in a general hospital might be a direct hernia recurrence risk factor, stressing the importance of experience in the administration of local anesthesia.

Cardiovascular disease accounts for most of the mortality associated with elective hernia repair (see chapter 17)<sup>239</sup>. Therefore, correctly performed local anesthesia might be preferable to regional and general anesthesia in frail patients with severe systemic diseases (ASA class III). An RCT has demonstrated that local anesthesia is associated with a superior ventilation and oxygenation pattern when compared with general and regional anesthesia<sup>649</sup>.

### **Discussion, Consensus, Clarification of Grading**

Evidence strongly supports the idea that local anesthesia has several advantages over general or regional anesthesia in elective reducible IH repairs. As suggested by hernia database analysis, hernia recurrence may be more common following operation employing local anesthesia. Experience in local anesthetic administration might negate this downside risk.

ASA class III patients undergoing IH repairs may benefit by the administration of local anesthetic over regional or general anesthetic. However, the evidence for this potential benefit is weak.

### **Key Question**

**KQ13.b** Are outcomes different when open inguinal hernia repairs are performed with regional versus general anesthesia?

## Introduction

The EHS Guidelines recommend against the use of spinal anesthesia in open anterior IH repairs in adults<sup>3</sup>. They also cite general anesthesia with short-acting agents combined with local infiltration anesthesia as a valid alternative to local anesthesia alone<sup>3</sup>.

## Statements and Recommendations

Statement	When compared with regional anesthesia, general anesthesia offers no clear advantages regarding the incidence of postoperative pain, postoperative nausea, cost, or patient satisfaction. Its use allows for faster patient discharge, which is of uncertain clinical significance. Some studies report a higher incidence of urinary retention with regional anesthesia.	⊗⊗⊗⊗
Statement	When compared with general anesthesia, regional anesthesia in patients aged 65 and older might be associated with a higher incidence of medical complications like myocardial infarction, pneumonia and venous thromboembolism.	⊗⊗⊗□
Recommendation	General or local anesthesia is suggested over regional in patients aged 65 and older.	⊗⊗□□ weak

## Evidence in Literature

Five reviews<sup>625–628,653</sup> and nine RCTs<sup>634,638,643,645,649,654–656</sup> comparing general to regional anesthesia were identified. The majority of these RCTs compared general, regional and local anesthesia<sup>634,638,643,649,656</sup>. Two of these five RCTs were excluded from this analysis since they mainly focused on pulmonary function assessment<sup>638,649</sup>. A 2002 review, based mostly on cohort studies, and including 26,653 patients undergoing hernia repair with either general or spinal anesthesia, did not report a statistically significant inter-group difference (3% versus 2.4% respectively)<sup>625</sup>.

A 2012 review of four randomized trials with 180 patients reported inconclusive results on early postoperative pain<sup>628</sup>. The review indicated that there might be a reduction in analgesic need in the early postoperative period following spinal anesthesia. The effect on postoperative nausea was similarly inconclusive with one<sup>634</sup> of two RCTs reporting a significant difference favoring spinal anesthesia while the other found no difference<sup>634,655</sup>.

The same 2012 review reported faster patient discharge after general anesthesia. No inter-group difference is reported in patient satisfaction scores. The incidence of urinary retention is not reported in the review.

The largest RCT<sup>643</sup> comparing local, general and regional anesthesia was not included in the



section of the 2012 review comparing general to regional anesthesia. The excluded RCT randomized 397 patients to either regional or general anesthesia. The majority of patients (62%) in both groups received local anesthetic infiltration as well. Pain, nausea, early postoperative complications, hospital length of stay, patient satisfaction and costs were not significantly different between groups<sup>629,643,646</sup>. However, regional anesthesia patients were significantly more likely to require bladder catheterization for urinary retention.

Another recent systematic review<sup>653</sup> excluded this RCT<sup>643</sup> as well because many patients underwent two different anesthetic modalities. This systematic review also reported a lower incidence of urinary retention in the general anesthesia group. Less early postoperative pain was seen in the regional anesthesia group. There were no differences between groups in the incidence of other complications.

An analysis done on 29,033 elective groin hernia repairs from the Danish Hernia Database found a higher incidence of medical complications in patients aged 65 years and older after regional anesthesia (1.17%) compared with general anesthesia (0.59%)<sup>657</sup>. Complications included myocardial infarction, pneumonia and venous thromboembolisms.

### Discussion, Consensus, Clarification of Grading

Some high-quality medical evidence is available to address **KQ16.b**. Several RCTs support the statements and recommendations above. Barring the questionable value of a statistically significant but clinically negligible faster patient discharge, no clear benefits of general over spinal anesthesia have been reported except in those 65 and older. Urinary retention might be more frequent following regional anesthesia. A moderate level of evidence supports the recommendation above.

### Key Question

**KQ13.c** Can surgical residents/registrars safely perform open inguinal hernia repair using local anesthesia?

### Introduction

Local anesthesia has several advantages to regional and general anesthesia. However, data from hernia registries suggest that the hernia reoperation rate may be higher after local anesthesia when compared with general or regional anesthesia<sup>51</sup>. Reoperation rates after hernia repair by private surgeons using local anesthesia are lower than those seen following primary IH repair in general hospitals. A higher level of expertise in local anesthesia administration seems to be associated with a lower reoperation risk. Does this also apply to physicians in the midst of learning curves like surgical residents/registrars?

### Statements

Statement	Open inguinal hernia repair under local anesthesia can be safely performed by trainees under supervision of surgeons experienced in the administration of local anesthesia.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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### **Evidence in Literature**

Five observational studies have examined complication rates after open IH repair under local anesthesia by trainees<sup>658–662</sup>. We excluded one of these articles from analysis because it only investigated results in patients operated on by fully trained surgeons who wanted to learn local anesthetic administration<sup>661</sup>. An Italian language article<sup>658</sup> was also excluded from analysis, leaving three English-language publications for review<sup>659,660,662</sup>. Two studies reported no complication rate differences including no difference in recurrence rate after 10 years of follow-up after trainee-performed operations versus consultant-performed operations despite use of higher local anesthetic volumes by trainees<sup>659,660</sup>. One study investigated the influence of experience on recurrence rates in 24 surgeons performing IH repair under local anesthesia<sup>662</sup>. Beginners, defined as those who have repaired less than six hernias under local anesthesia, had a significantly higher recurrence rate. The study authors concluded that beginners should be closely supervised during their first six operations.

These few studies suggest that in the case of IH repairs done under local anesthesia, experience in local anesthesia administration influences recurrence/reoperation rates. Trainees can safely perform these operations but supervision by a surgeon with the requisite experience is necessary to achieve optimal outcomes.

## **Chapter 14 Early Postoperative Pain Prevention and Management**

P. Nordin and A.R. Wijsmuller

### **Introduction**

Several approaches to postoperative pain management have been studied including various medical treatments and interventions like the use of local anesthetics. This chapter reviews the literature on preoperative, perioperative, and postoperative interventions designed to treat pain after open groin hernia repair.

### **Key Questions**

**KQ14.a** Do preoperative or perioperative local anesthetic methods affect patients' pain experiences after open groin hernia repair?

**KQ14.b** Which is the most effective oral analgesic pain management regimen after open or endoscopic groin hernia repair?

### **Statements and Recommendations**

Statement	When general or regional anesthesia is used, the addition of local anesthetic field blocks of the ilioinguinal and iliohypogastric nerves and/or subfascial and subcutaneous infiltration reduces early postoperative pain scores and the need for other analgesics.	☒☒☒☒	
Statement	Long-acting local anesthetics are preferable to short-acting local anesthetics but the timing of field blocks and/or infiltration—either preoperatively or at wound closure—has no proven effect on the occurrence of postoperative pain.	☒☒☐☐	
Statement	NSAID or selective COX-2 inhibitors reduce postoperative pain and when given with paracetamol reduce postoperative pain further.	☒☒☒☒	
Recommendation	Preoperative or perioperative local anesthetic measures like field blocks of the inguinal nerves and/or subfascial/subcutaneous infiltration are recommended in all open groin hernia repairs.	☒☒☒☒	strong
Recommendation	Use of a conventional NSAID or a selective COX-2 inhibitor <u>plus</u> paracetamol is recommended in open groin hernia repairs provided that there are no contraindications.	☒☒☒☒	strong

## Evidence in Literature

Herniorrhaphy postoperative pain prevention measures include the use of preoperative and intraoperative local anesthetic infiltration and/or preoperative or intraoperative field block and paravertebral block and conventional NSAIDs or selective COX-2 inhibitors.

The use of a preoperative or intraoperative field block (mostly of the ilioinguinal and iliohypogastric nerves) with or without local wound infiltration is superior to placebo or no treatment for reducing early postoperative pain scores and the need for supplementary analgesics<sup>663–667</sup>.

Seven randomized trials reported that field block of the ilioinguinal and iliohypogastric nerve with wound infiltration was superior to no treatment or placebo for reducing postoperative pain scores and supplementary analgesic requirements<sup>668–674</sup>.

A 2012 review<sup>628</sup> summarized four randomized trials comparing wound infiltration with local anesthetic to placebo<sup>656,675–677</sup>. Wound infiltration was found to be superior to placebo for

reducing early postoperative pain scores and the use of supplementary analgesics. Wound infiltration also lengthened the time to first analgesic request.

A 2015 randomized trial of wound infiltration versus placebo found no difference in pain incidence three months postoperatively<sup>678</sup>.

A prospective, double-blind, randomized trial compared subfascial to subcutaneous local anesthetic infiltration and reported improved early postoperative pain scores after subfascial infiltration<sup>679</sup>. Another randomized study compared combined subfascial and subcutaneous infiltration to subcutaneous or subfascial infiltration alone. Combination infiltration resulted in improved early postoperative pain scores, less supplementary analgesic need and longer time-to-first-analgesic request<sup>680</sup>.

Two studies compared local anesthetic infiltration to placebo or no treatment and found local infiltration superior with respect to early postoperative pain and supplemental analgesic use<sup>681,682</sup>. Three studies investigated local anesthetic timing, comparing preoperative to at/near-wound-closure infiltration<sup>683-685</sup>. Two of the three studies reported no differences in early postoperative pain and supplemental analgesic use after preoperative field block versus at-wound-closure field block during general anesthesia<sup>683,684</sup>. The third study compared pre-incisional and before-wound-closure infiltration during general anesthesia concluded that pre-incisional infiltration with lidocaine was a more effective method of providing postoperative analgesia<sup>685</sup>. The 2012 review referenced above concluded that preoperative and at-wound-closure local anesthetic regimens had equal benefit in reducing pain scores and supplemental analgesic use<sup>628</sup>.

Two studies found that ultrasound-guided nerve blocks (involving the iliohypogastric/ilioinguinal nerves) were superior to anatomic-landmark nerve blocks at providing effective analgesia<sup>686,687</sup>.

Paravertebral nerve blocks (PVBs) are established methods of providing analgesia to thoracic- and abdominal-surgery patients including those undergoing groin hernia repair. A PVB has the potential to offer sustained pain relief with minimal side effects. One systematic review<sup>688</sup> and three randomized studies<sup>689-691</sup> found a tendency to less postoperative pain in PVB-patients when compared with general-anesthesia and spinal-anesthesia patients.

The transversus abdominis plane (TAP) block is a relatively new regional anesthetic technique developed in an attempt to reduce postoperative pain. It has evolved from a landmark technique to an ultrasound-guided one. Four randomized studies comparing TAP blocks with either placebo, local anesthetic infiltration, or no treatment reported conflicting results with respect to early postoperative pain and analgesic use<sup>125,668,692,693</sup>. A 2010 Cochrane Database Systematic Review found only limited evidence to suggest that the use of perioperative TAP blocks is opioid sparing or reduces pain scores after abdominal surgery<sup>694</sup>.

In addition to the preoperative and intraoperative pain prevention and treatment methods above, non-opioid and non-steroidal anti-inflammatory medications (acetaminophen, NSAIDs and selective COX-2 inhibitors) should be used for postoperative pain management<sup>695–699</sup>. Paracetamol (Acetaminophen) has insufficient effect as single-agent therapy for moderate to severe pain. However, the combination of paracetamol and a non-steroidal anti-inflammatory drug, given in a timely manner, seems to be optimal and provides sufficient analgesic during the early recovery phase provided that there is no contraindication<sup>628,700</sup>.

Opioids may cause adverse effects such as nausea, vomiting, and constipation, amongst others which may delay postoperative recovery. Therefore, non-opioid analgesics should be used whenever possible. However, opioids can be used for moderate- or high-intensity pain, in addition to non-opioid analgesia or when the combination of an NSAID and paracetamol is not sufficient or is contraindicated<sup>701</sup>.

Several small studies of varying quality seem to indicate that local anesthetic administration via intra-wound catheters by repeat bolus or continuous infusion is more efficacious than placebo at reducing postoperative pain<sup>702–707</sup>. Potential benefits and risks of this technique need further study with RCTs and other means.

## **Discussion and Grading Clarification**

Inguinal hernia repair results in pain postoperatively and the optimal method(s) to treat this pain remain(s) controversial. However, it is clear that local anesthetic field blocks and subfascial and/or subcutaneous local infiltration reduces early postoperative pain scores and the need for supplemental analgesics. Therefore, when general or regional anesthesia is used, local anesthetic field blocks and infiltration is recommended in all open groin hernia surgeries. Additionally, the combination of a conventional NSAID or a selective COX-2inhibitor plus paracetamol reduces postoperative pain and is also recommended.

A weakness in the review presented in this chapter stems from the variation in quality of the available randomized trials. Although postoperative pain was our focus, it was not always the primary endpoint of the included studies.

There is strong evidence for preoperative and intraoperative inguinal field blocks and wound infiltration with seven randomized studies showing superiority to no treatment or to placebo. Four randomized trials found wound infiltration superior to placebo. Provided that there is no contraindication, the use of a conventional NSAID or a selective COX-2 inhibitor is also recommended with four randomized trials and one review showing reduced postoperative pain when compared to placebo. There is also strong evidence to support the use of paracetamol in

combination with conventional NSAIDs/selective COX-2 inhibitors. Opioids are recommended in limited circumstances as described above.

## Chapter 15 Convalescence

T. Bisgaard and L.N. Jorgensen

### Introduction

Convalescence duration—defined as sick leave from work and time away from leisure—is an important feature of the recovery phase following IH surgery. However, most studies have not investigated the impact of recommendations on short duration convalescence.

### Key Question

**KQ15.a** What is the recommended duration of convalescence following uncomplicated inguinal hernia repair

### Statement and Recommendation

<b>Statement</b>	Physical activity restrictions are unnecessary after uncomplicated inguinal hernia repair and do not effect recurrence rates. Patients should be encouraged to resume normal activities as soon as possible.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *Upgraded
<b>Recommendation</b>	An early return to normal activities can safely be recommended.	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Strong *Upgraded

### Evidence in Literature

The literature search identified 327 studies of which we included one systematic review, 14 RCTs, three cohort studies and four case-control studies.

### Discussion

Surgeons' recommendations for physical activity restrictions and/or sick leave duration are highly variable, rarely evidence-based, and greatly affect the duration of absence from normal activity<sup>148,708–710</sup>. No study has demonstrated that early return to normal activities and work after IH repair increases hernia recurrence risk or complications.

One nationwide RCT of 2,365 patients with convalescence duration as the primary outcome found that a short duration of convalescence (even as short as one day) following open IH repair may be recommended without increasing hernia recurrence risk<sup>148</sup>.

Pain and wound-related problems are the most often cited reasons for not resuming work or leisure activities as recommended (evidence level – high)<sup>148</sup>. A 2012 study of 162 laparoscopic IH repair patients found that convalescence duration was a median of five days (range 1 to 40) from work and three days (range 1 to 49) from leisure activities when the recommendation was for one day<sup>709</sup>. Patient expectation preoperatively for time off work was the only independent factor that predicted prolonged convalescence. Postoperatively, self-arranged planned sick leave, and complaints of pain and fatigue were the primary reasons for not resuming normal activities within the first three days after operation (evidence level – low)<sup>709</sup>.

In studies where duration of convalescence was secondary outcome using non-restricted recommendations ( $\leq 2$  days) reported 1 week absence from domestic activities<sup>209,218,241,242,256,711–713</sup>, one to two weeks absence from work<sup>209,218,242,246,250,253,256,277,288,711,713–718</sup>, and one to three weeks after physical activities including sports<sup>209,242,250,288,711,717</sup> (*low to moderate level of evidence*).

The available medical evidence supports the idea that work and leisure activities can be resumed by most patients within three to five days following elective laparoscopic or open IH repair without risk of hernia recurrence or other complications.

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